UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessment for the insecticide lindane. The Agency has revised the human health and environmental effects risk assessments based on the comments received during the public comment period and additional data received from the registrant. Based on the EPA's revised risk assessments for lindane, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of lindane. EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of lindane, and its associated human health and environmental risks. The Agency's decision on the individual chemical lindane can be found in the attached document entitled, "Reregistration Eligibility Decision for Lindane" which was approved on July 31, 2002. There will be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register.

A Notice of Availability for the reregistration eligibility decision (RED) document for lindane is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED document and all supporting documents are available on the internet at http://www.epa.gov/pesticides/reregistration/lindane.

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. As part of this process, the preliminary risk assessments were made available to the public for comment on August 29, 2001. Based on the information received, the risk assessments were revised and made available again to the public on January 31, 2002 for input on measures to reduce risks. In cooperation with the U.S. Department of Agriculture, the Agency also conducted a close-out conference call on July 31, 2002 with various stakeholders to discuss the risk management decisions and resultant changes to the lindane labels.

Please note that the lindane risk assessment and the attached RED document concern only this particular pesticide. FQPA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA did not perform a cumulative risk assessment as part of this reregistration review for lindane because it has not yet determined if there are any other chemical substances that have a mechanism of toxicity common with that of lindane. For purposes of this reregistration decision, EPA has assumed that lindane does not have a common mechanism of toxicity with other substances.

This document contains a generic and product-specific Data Call-In (DCI) that outlines further data requirements for this chemical. Note that registrants of lindane must respond to DCIs issued by the Agency within 90 days of receipt of this letter. This RED document also contains labeling changes for lindane products. It is necessary that end-use product labels be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by lindane. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the proposed label changes, please contact the Chemical Review Manager for lindane, Mark T. Howard at (703) 308-8172. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen Jones at (703) 308-8047.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

REREGISTRATION ELIGIBILITY

DECISION

for

LINDANE

CASE 315

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Lindane Team

Office of Pesticide Programs:

Health Effects Risk Assessment
Becky Daiss
Thurston G. Morton
Suhair Shallal
David Jaquith
Ray Kent
Sanjivani Diwan

Environmental Fate Risk Assessment
Nicholas Federoff
Faruque Khan
Jose Melendez
Dirk Young

Biological and Economics Division
David Brassard
Istanbul Yusuf

Registration Division Support
Dana Pilit
George Larocca

Risk Management
Mark T. Howard
Deborah Smegal
Michael Goodis

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GLOSSARY OF TERMS AND ABBREVIATIONS

AERS	Adverse Event Reporting System
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
aRfD	Acute Reference Dose
BCF	Bioconcentration Factor
CIEL	Centre International d'Etudes du Lindane
cPAD	Chronic Population Adjusted Dose
CFR	Code of Federal Regulations
cRfD	Chronic Reference Dose
CSFII	Continuing Surveys for Food Intake by Individuals (USDA)
D	Dust
DAF	Dermal Absorption Factor
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DWECs	Drinking Water Estimated Concentrations
DWLOC	Drinking Water Level of Comparison
E-FAST	Exposure and Fate Assessment Screening Tool
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division
EIIS	Ecological Incident Information System
EPA	U.S. Environmental Protection Agency
FC	Flowable Concentrate
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIRST	FQPA Index Reservoir Screening Tool
FQPA	Food Quality Protection Act
FR	Federal Register
FRN	Federal Register Notice
FWS	U.S. Fish and Wildlife Service
GENEEC	Tier I Surface Water Computer Model
HED	Health Effects Division
HCH	Hexachlorocyclohexane
IADN	Integrated Atmospheric Deposition Network
IDS	Incident Data System
IUPAC	International Union of Pure and Applied Chemistry
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOQ	Limit of Quanitation

mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NARAP	North American Regional Action Plan
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fisheries Service
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
OPP	EPA Office of Pesticide Programs
PAD	Population Adjusted Dose
PAM	Pesticide Analytical Method
PD	Public Document
PDCI	Product-Specific Data Call-In
PHED	Pesticide Handler's Exposure Data
POTW	Publically Owned Treatment Works
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRB	Product Reregistration Branch
PRZM/ EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPAR	Rebuttable Presumption Against Reregistration
RQ	Risk Quotient
RTU	Ready-to-Use Liquid
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SRRD	Special Review and Reregistration Division
TBD	To Be Determined
TRAC	Tolerance Reassessment Advisory Committee
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey

Executive Summary

This document addresses whether pesticide products containing the active ingredient, lindane, are eligible for reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and whether existing tolerances for residues of lindane in food and feed may be reassessed under the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA).

Lindane was initially registered by USDA in the 1940's and over the years since has been approved for use on a wide variety of fruit and vegetable crops (including seed treatment), ornamentals, tobacco, greenhouse vegetables and ornamentals, forestry, farm animal premises, and other uses. Tolerances were established for a wide variety raw agricultural commodities; see 40 CFR sec. 180.133. A number of reviews and regulatory actions affecting lindane have taken place in the last twenty years with the result that there are now only a very limited number of products containing lindane registered for use as seed treatments. All other uses of lindane have been canceled.

EPA has determined that all existing tolerances for lindane should be revoked. Consistent with longstanding EPA policy, the reason for revoking these tolerances is that they are no longer necessary because all lindane products for which the tolerances were originally established have been canceled. In reaching this conclusion, the Agency does not need to make any determination whether the exposures permitted under these tolerances would meet the FFDCA safety standard.

EPA has determined that a number of changes to the terms and conditions of registration of the seed treatment products are necessary to prevent "unreasonable adverse effects on the environment." These changes include such measures as reduced maximum application rates, use of additional personal protective equipment, and discontinue on-farm use of the dust formulation for some crops. In addition, EPA has determined that the use of lindane for seed treatment is likely to result in residues in raw agricultural commodities derived from plants grown from seeds treated with lindane. Therefore, new tolerances are required before the currently registered lindane products may be reregistered. EPA has identified additional data needed to characterize lindane metabolites in order to complete its assessment of potential dietary risks. In summary, EPA finds that the currently registered lindane seed treatment products would be eligible for reregistration if the registrants make the changes to the terms and conditions specified in this document and provide the required data, and EPA is able to establish all required tolerances for residues of lindane in food.

EPA notes that the establishment of new tolerances for the seed treatment uses of lindane is conditioned on: 1) the receipt and review of additional data to characterize lindane metabolites; and 2) EPA’s ability to make a determination that establishing the new tolerances meets the safety standard in FFDCA. Because EPA does not know what the data will indicate about lindane metabolites, and for other reasons, EPA is unable to determine whether it will be able to make a determination that new tolerances for lindane would be safe.

FFDCA sec. 408(b)(2)(A)(i) provides that EPA may establish a new tolerance "only if .... the tolerance is safe." The statute defines "safe" to mean "that there is a reasonable certainty that

no harm will result from aggregate exposure ....." "Aggregate exposure" includes both exposure to residues in food "and exposure from other non-occupational sources." See § 408(b)(2)(D)(vi).

In light of these statutory provisions, EPA is considering whether the statute requires the Agency to include in its safety assessment those exposures resulting from the use of lindane in pharmaceutical products. Lindane is currently approved by the Food and Drug Administration for use in pharmaceutical products intended to control head lice and scabies. EPA and FDA have worked together to examine the available data to assess the potential of lindane pharmaceuticals to cause adverse effects, sharing our assessments and commenting on the other agency's assessments. As discussed more fully later in this document, although the information for assessing risks is limited, the exposure and risk assessment indicates that the use of lindane for head lice control does not pose risks of concern. The limited information available on the scabies product, however, suggests that there is some possibility a portion of the patient population using lindane for scabies control may experience adverse effects. FDA has taken steps – including stronger warnings, clearer use directions, and other measures – to limit such potential adverse effects. Based on these additional steps, FDA has concluded that the therapeutic benefits of the lindane pharmaceutical products outweigh the limited potential to cause adverse effects in the patient population. Therefore, FDA regards these products as safe and effective for the purposes for which they were approved.

The existence of pharmaceutical sources of exposure to lindane raise questions of public policy and statutory interpretation that have not been resolved. These questions include: whether "aggregate exposure" encompasses exposures resulting from the use of lindane in pharmaceutical products; and if so, whether there is any reasonable statutory interpretation that could avoid apparently questionable public policy results. EPA is particularly concerned that the statute be interpreted and applied in a manner that yields results that are protective of public health and consistent with common sense. If sec. 408 were interpreted to cover exposure from pharmaceutical uses, then EPA might never be able to establish new tolerances, or to leave existing tolerances in effect, for a substance that is used both as a pesticide and a pharmaceutical product, if the pharmaceutical product caused adverse effects in humans. This result could occur regardless of the level of risk posed by the exposures permitted under the tolerance(s) and their associated pesticide registrations, and even though the pharmaceutical product has been deemed "safe and effective." In other words, EPA would be concerned about relying on an interpretation of FFDCA sec. 408 that could compel regulatory actions which would have no impact on the major source of exposure, and where the source of such exposure is fully regulated and approved under a public health standard.

EPA is interested in additional information and views that would help it determine how to approach the issues discussed above. First, because there are many uncertainties about the extent of risk from the use of lindane for scabies control, EPA encourages the development of additional information that might support a more certain assessment of the potential risks of the lindane scabies product. EPA is also continuing to pursue a dialogue with FDA to refine aspects of the analysis. Second, EPA invites public comment on the regulatory and public policy questions raised by the use of chemicals, such as lindane, both as pesticides and pharmaceuticals. There will

be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register.

Finally, EPA notes that, in addition to the reviews of lindane described above, the governments of Canada, Mexico and the United States are also considering joint actions to reduce the risks associated with lindane. Specifically, the three countries, working through the Commission for Environmental Cooperation (CEC), established by the North American Agreement for Environmental Cooperation, have agreed to develop a North American Regional Action Plan (NARAP) on lindane (CEC Council Resolution 02-07). The purpose of the NARAP is to reduce environmental and health risks from lindane on a regional basis. The Agency is also aware that internationally, other countries are taking significant actions to reduce and eliminate risks from lindane.

Overall Risk Summary

The Agency's human health risk assessment for lindane indicates some risk concerns. Both acute and chronic risks from food alone are low and not of concern to the Agency. Drinking water risk estimates based on screening-level models from both ground and surface water exposures are also low and do not pose a risk concern for drinking water exposure. There are risk concerns for workers with on-farm use of the dust formulation to treat certain seeds. All occupational risks of concern are mitigated with the use of certain personal protective equipment or engineering controls. Ecological risks from the seed treatment of lindane are of concern; however, the Agency believes the assessment is conservative and overestimates the risks. The pharmaceutical use of lindane to treat lice does not pose risks of concern to the Agency, but the use of lindane to treat scabies does pose a risk of concern based on EPA's risk assessment.

Dietary Risk – Food

The acute dietary (food) risks are less than 100% of the acute Population Adjusted Dose (aPAD) for the general U.S. population and all population subgroups. Infants (<1 year), the most highly exposed population subgroup, are estimated to be exposed to lindane at a level of 17% of the aPAD. The chronic dietary (food) risks are also less than 100% of the chronic Population Adjusted Dose (cPAD) for the general U.S. population and all population subgroups usually considered. Children (1-6 years), the most highly exposed population subgroup, are estimated to be exposed to lindane at a level of 11% of the cPAD.

Because of the persistence of lindane and its long-range atmospheric transport potential, lindane is detected in colder regions, such as the Arctic, where the compound becomes less volatile. Because indigenous peoples of the Arctic region of the U.S. (Alaska) rely heavily on game for their food source, the Agency performed a supplementary chronic dietary exposure and risk assessment for these subsistence diets. For indigenous people of Alaska, the chronic dietary risks are generally not of concern. For the most highly exposed subpopulation, children (1-6 years), the subsistence diet heavy in game results in estimated lindane exposures ranging from 13-65% of the cPAD, with one scenario at 138% of the cPAD. The highest estimate was based on

highly conservative assumptions, including children eating blubber every day for six years, which probably overestimates dietary risk. An acute dietary assessment is not possible for indigenous people of Alaska at this time, because the Agency does not have information on a typical day's diet. Nevertheless, based on limited residue data, the Agency believes acute dietary risks are unlikely to be of concern.

Dietary Risk – Drinking Water

Drinking water exposure to lindane can occur through ground and surface water contamination. EPA used models to conduct a screening-level assessment of potential high-end estimates of lindane concentrations from seed treatment uses in surface and ground water sources of drinking water. Based on currently registered uses, the highest drinking water estimated concentrations (DWECs) of lindane in surface water sources are 0.98 ppb for acute exposure and 0.46 ppb for chronic exposure. The ground water DWEC for lindane is 0.011 ppb for both acute and chronic exposure.

Pharmaceutical Use Risk

Lindane has been approved by the FDA as a prescription drug to treat lice and scabies. EPA has conducted an assessment of these uses to determine the risk of a lice or scabies treatment. Based on the Agency's current understanding of available data, the Agency does not believe that lindane pharmaceutical products used for treatment of lice pose human health risks of concern, when used in accordance with directions provided on the label. However, based on other blood-level analyses, the Agency cannot conclude at this time with reasonable certainty that exposure to lindane through scabies treatment will not result in unacceptable exposure and risk.

The Agency also assessed the risks associated with estimated concentrations of lindane in surface water used as a source of drinking water which might result from consumer use of lindane for both lice and scabies treatments. Based on reported lindane concentrations of discharged effluent from water treatment facilities in California used in a model to predict dilution in receiving streams, the acute and chronic DWECs are extremely low (10^{-5} to 10^{-4} ppb range).

Risk from All Registered Pesticide Lindane Exposures

To assess risks from all lindane exposures, the Agency combined risk from food and drinking water exposure only. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to determine whether DWECs exceed this level. DWECs that are less than the corresponding DWLOC are not of concern to the Agency. Because there are no registered residential or other non-occupational uses of lindane that need to be considered for regulatory purposes at this time, the assessment for lindane combines exposures from food and drinking water sources only. For the agricultural seed treatment uses of lindane, both acute and chronic DWECs are below the corresponding DWLOCs for all drinking water sources, and are not of concern to the Agency.

Occupational Risk

Occupational exposure to lindane is of concern to the Agency for some worker scenarios, necessitating the need for certain measures to mitigate these risks. In particular, the on-farm handling of the lindane dust formulation to mix/load and plant treated seed results in risks of concern (MOEs < 100). To mitigate these risk concerns, on-farm treatment of wheat, barley, oats, and rye seeds with the dust formulation of lindane is prohibited. Because of the lower seed planting rate, the on-farm treatment of corn and sorghum seeds with the lindane dust formulation is permitted, provided additional personal protective equipment (PPE) is utilized. Commercial treatment of seeds with the liquid formulation for all registered uses is permitted. Specific PPE for workers that are to treat seeds on-farm or commercially, and handle and plant treated seeds are specified in this RED document. Also, the Agency has no risk concerns for post-application exposures to agricultural workers, and no risk mitigation measures are necessary beyond a 24 hour restricted entry interval (REI). However, provided the soil is not disturbed and there is no contact with the treated seeds, workers may enter the planted field during the 24-hour REI.

Ecological Risk

The Agency's assessment suggests that the use of lindane can result in adverse acute and chronic effects to terrestrial organisms, and adverse acute effects to aquatic organisms. Lindane is a potential endocrine disruptor in birds, mammals, and possibly fish.

The registrant has agreed to reduce the maximum application rate to corn, which is a use that resulted in the highest risk to birds. However, avian (dietary) aversion toxicity studies and a field study suggest that birds are repelled by treated seeds; hence, the Agency believes that the risk to birds by treating certain seeds with lindane are lower and not of concern. The risks to mammals are also further reduced with the lowering of the maximum application rate to corn. Moreover, the Agency believes that the risks for local populations of mammals in areas where lindane treated seeds are planted are low, and that although there are no data available to demonstrate that mammals avoid consuming lindane treated seeds as do birds, it is possible that mammals will be similarly adverse to eating seeds treated with lindane. The Agency also has acute risks of concerns for freshwater fish and invertebrates, and estuarine marine invertebrates. However, the screening-level model used to assess these risks has likely produced highly conservative estimates which overestimated the environmental concentrations and resulting risks to aquatic species. Actual aquatic risks are expected to be lower and not of concern, and the Agency and is requiring data to confirm this determination.

Risk Management Decision

The Agency will revoke all existing lindane tolerances because all lindane products for which the tolerances were originally established have been cancelled. The Agency has also determined that the currently registered lindane seed treatment products would be eligible for reregistration if the registrants make the changes to the terms and conditions specified in this document and provide the required data, and EPA is able to establish all required tolerances for residues of lindane in food. This RED document includes guidance and time frames for complying with any label changes for products containing lindane.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment for all existing tolerances. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996.

FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Lindane is an organochlorine chemical. Although chemical class is not necessarily equivalent to a common mechanism of action, in some cases, chemicals within the same class have been shown to share a common mechanism of action and are being considered together for purposes of a cumulative assessment (e.g., the organophosphates). The Agency has not performed a cumulative risk assessment as part of this reregistration review of lindane, because it has not determined if there are any other chemical substances to have a common mechanism of toxicity. If the Agency identifies other substances that share a common mechanism of toxicity with lindane, then the cumulative risks of these chemicals will be considered.

This RED document for lindane presents the Agency's revised human health and ecological risk assessments; the tolerance reassessment; and the RED for lindane. This document consists of five sections. Section I contains the regulatory authority and framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V identifies label changes necessary to implement the risk mitigation measures. Finally, among the Appendices is a description of the revised use patterns, generic and product-specific Data Call-In (DCI) information. The revised risk assessments and other supporting technical documents are not included in this document, but are available on the Agency's web page at http://www.epa.gov/pesticides/reregistration/lindane and in the public docket.

II. Chemical Overview

A. Regulatory History

Lindane is an organochlorine insecticide that was first registered with USDA for use as a pesticide in the 1940's. Lindane was registered for a wide variety of fruit and vegetable crops (including seed treatment), ornamentals, tobacco, greenhouse vegetables and ornamentals, forestry, Christmas tree plantations, hardwood log dips, livestock dips, farm animal premises, domestic outdoor and indoor use by homeowners (including dog dips, household sprays, and shelf paper), commercial food or feed storage areas and containers, wood or wooden structure sites, and human skin/clothing (military use only). Lindane was manufactured in the U.S. until 1977. All other lindane used in this country was imported from France, Germany, Spain, Japan, India, Romania, and China.

In 1977, EPA initiated a Rebuttable Presumption Against Registration (RPAR) review of lindane, which is currently termed as Special Review. The lindane RPAR was triggered based upon questions of oncogenicity, fetotoxicity/ teratogenicity, reproductive effects (i.e., litter size and testicular effects), its potential to cause blood dyscrasias (including aplastic anemia), and acute toxicity to wildlife. Position Documents (PDs) were published in 1977 (PD-1), in 1980 (PD-2/3), and in 1983 (PD-4). A Notice of Intent to Cancel Pesticide Products Containing Lindane was issued October 19, 1983 (48 *FR* 48512). All of the RPAR triggers were either rebutted or withdrawn except for oncogenicity. As a result of a risk/benefit analysis based on oncogenic risks, the RPAR decision resulted in the phasing out of the registrations for lindane smoke fumigation devices for indoor domestic use, and in the cancellation of lindane dog dips for the control of pests other than mites. The dog dip cancellation was challenged, and subsequently the dog dip use for pests other than mites was permitted for veterinary use.

In September 1985 the Agency issued the Lindane Registration Standard that reflected a reassessment of the database, required additional studies to support the lindane registration and conveyed concerns for applicator exposure and secondary exposure from treated structures or animals. In addition, the restricted use classification for certain use patterns, which have since been cancelled, was continued from the PD-4, along with expanding the protective clothing requirements for certain uses. Because of dietary exposure concerns to lindane and the lack of data to support the then current tolerances, no additional lindane tolerances were to be considered until the data gaps identified in the Registration Standard were filled. Although the Agency's Carcinogen Assessment Group classified lindane in the B2-C range as a *Probable/Possible Human Carcinogen*, the Agency decided to regulate lindane as a class C carcinogen pending the receipt of further studies. The data have since been provided, and the Agency has classified lindane as "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." Because of concerns about the potential for exposure to non-target aquatic organisms, a prohibition against aerial application and special disposal directions for used dip solutions were carried forward from the 1983 Notice of Intent to Cancel. Labeling changes intended to reduce the exposure of birds to lindane treated seed were also carried forward.

After the Registration Standard was issued in 1985, the registrant task force, Centre International d'Etudes du Lindane (CIEL), was involved in conducting studies and negotiating with EPA over study requirements and possible voluntary cancellations. Between 1993 and 1998, long-range transport and environmental concerns about lindane increased. In response, the lindane technical registrants requested voluntary deletion all uses except seed treatment on 19 agricultural crops. These crops are: barley, broccoli, Brussels sprouts, cabbage, cauliflower, celery, collards, corn, lettuce, kale, kohlrabi, mustard greens, oats, radishes, rye, sorghum, spinach, Swiss chard, and wheat. These use deletions are reflected in four Notices of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations, were published in the Federal Register on August 26, 1998 (Volume 63, Number 165, Page 45481-45483); September 30, 1998 (Volume 63, Number 189, Pages 52257-52260); December 2, 1998 (Volume 63, Number 231, Page 66542-66543); January 27, 1999 (Volume 64, Number 17, Pages 4096-4097); and August 18, 2000 (Volume 65, Number 161, Page 50524-50526).

The use deletions from the four preceding Federal Register Notices are: livestock (including cattle, goats, horses, sheep, mules, hogs, mules, and sheep); pet care uses; ornamentals (trees and shrubs); turf (lawns & golf courses); recreational areas; uncultivated areas, fallow or agricultural areas; commercial transportation facilities; food processing handling/storage areas/plants; grain/cereal/flour bins and storage areas; farm or agricultural structures (including barns; wood-protection treatment of buildings); wood treatment, stored timber and lumber treatment; military use on human skin and clothing. Furthermore, the following food and/or feed and/or fiber crop uses were deleted: almonds, alfalfa, apples, apricots, asparagus, beans (all types), beets, cantaloupe, carrots, cherries, clover, cotton, cucumbers, cucurbits (all types), eggplant, flax, grapes, guave, lentils, mangoes, melons, mint, mushrooms, nectarines, okra, onions, peaches, peas (all types), pecans, pears, peppers, pine apples, plums, prunes, pumpkins, quinces, rape, safflower, soybeans, squash, (all types), strawberries, sudan grass, sugar beets, summer squash, sunflower, tomatoes, and watermelon. In addition, tobacco use was also cancelled.

Currently, the only food/feed use of lindane which is being supported for reregistration is seed treatment on barley, corn, oats, rye, sorghum, and wheat. Since the 1998 and 1999 use deletions, the registrants are no longer interested in supporting the seed treatment use on broccoli, Brussels sprouts, celery, cabbage, cauliflower, collards, kale, kohlrabi, mustard greens, lettuce, radishes, spinach, and Swiss Chard for reregistration. In 2001 and 2002, the technical registrants have submitted letters requesting voluntary cancellation of these crops. A Federal Register Notice announcing use deletions from the technical labels registered to Inquinosa was published on June 13, 2002 (Volume 67, Number 114, Page 40730-40732). Another notice announcing these use deletions for the other technical lindane registrations was issued on July 17, 2002 (Volume 67, Number 137, Page 46976-46978]. Additional notices from other technical registrants announcing these use deletions from lindane labels are to be issued soon.

In addition, during the reregistration process for lindane, the registrant submitted a petition for the use of lindane on canola seeds. The risks associated with this proposed use were assessed and included in this RED document and supporting technical documents for

informational purposes. The decision whether to grant the petition and register canola as a new use is outside the scope of this RED and will be made separately by the Agency.

Lindane is also available, and regulated by the U.S. Food and Drug Administration (FDA), for the pharmaceutical treatment of scabies and head lice. A 1% lindane lotion is available for the treatment of scabies, and a 1% lindane shampoo is available for the treatment of head lice. Both uses have been on the market since 1947, but was labeled as a second line therapy in 1995 after a review by the FDA.

International Agreements and Treaties

Lindane, among other pollutants, is subject to bilateral and multilateral international agreements and treaties. These include:

- The Great Lakes Binational Toxics Strategy, a voluntary agreement between the U.S. and Canada. Lindane is listed as a Level II substance. Level II substances are those for which one country or the other has grounds to indicate its persistence in the environment, potential for bioaccumulation, and toxicity. Website: http://www.epa.gov/glnpo/bns/

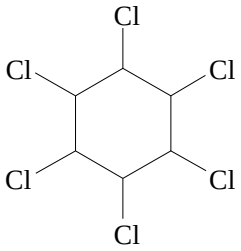
- The Persistent Organic Pollutants (POPs) Protocol to the Convention on Long-Range Transboundary Air Pollution (LRTAP), a legally-binding regional treaty. Lindane is listed as an annex II substance. Annex II includes POPs scheduled for restrictions on use. Website: http://www.unece.org/env/lrtap/

- The Rotterdam Convention on Prior Informed Consent (PIC), a procedure for certain hazardous chemicals and pesticides in international trade, a legally-binding global treaty. Lindane is a chemical subject to the PIC procedure. Website: http://www.fao.org/waicent/FaoInfo/Agricult/AGP/AGPP/Pesticid/PIC/pichome.htm

- The North American Free Trade Agreement (NAFTA). As a component of NAFTA and efforts to harmonize pesticide product registration, lindane is undergoing a joint reregistration review between the U.S. and Canada. Also, under the NAFTA environmental side agreement, the US, Canada, and Mexico will develop a North American Regional Action Plan (NARAP) on lindane beginning in 2002. Website: http://www.cec.org/programs_projects/pollutants_health/smoc/

B. Chemical Identification

- **Common Name:** Lindane
- **Structure:**



- **Chemical Name:** gamma isomer of Hexachlorocyclohexane
- **Chemical family:** Organochlorine
- **Case number:** 0315
- **CAS registry number:** 58-89-9
- **OPP chemical code:** 009001
- **Empirical formula:** $C_6H_6Cl_6$
- **Molecular weight:** 290.9
- **Trade and other names:** Agrox Premiere®, Germate Plus®, Isotox F®, and Kernel Guard®, DB Green®, Vitavax®, Enhance®, Seed Shield®.
- **Basic manufacturer:** Inquinosa Internacional, SA
- **Physical Chemical and Environmental Fate Properties:**

Lindane is a white crystalline solid with a melting point of 112-113°C, specific gravity of 1.85, octanol/water partition coefficient (K_{ow}) of 3135, and vapor pressure of 9.4 x 10^{-6} mm Hg at 20°C. Lindane is slightly soluble in water (10 ppm at 20°C) and in most organic solvents, including acetone and aromatic and chlorinated hydrocarbons. Lindane is only slightly soluble in mineral oils. Lindane is stable to light, heat, air, and strong acids, but decomposes in alkali solutions to trichlorobenzenes and HCl.

Fate studies show that lindane is both moderately mobile (mean K_{oc} = 1368) and highly persistent (soil half life of 2.6 years). It is resistant to photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial actions. Degradates are predominantly pentachlorocyclohexane, 1,2,4,-trichlorobenzene, and 1,2,3-trichlorobenzene.

C. Use Profile

The following information is based on the currently registered agricultural uses of lindane:

Type of Pesticide: Insecticide

Summary of Use Sites:

Food/Feed: Seed treatment for barley, corn, oats, rye, sorghum, and wheat.

Non-Food Agricultural: No other agricultural use sites.

Residential: None.

Pharmaceutical: Prescription lice and scabies treatments.

Other: None.

Use Classification: General use.

Target Pests: Wireworm; and less effective against flea beetles, seed corn maggots, seed corn beetle and white grubs.

Formulation Types Registered: Dust (D), emulsifiable concentrate (EC), flowable concentrate (FC), and liquid ready-to-use (RTU).

Method and Rates of Application:

Equipment: Liquid seed treater; planter/seed box; air seed treater; canister tube applicator, and slurry-type seed treater.

Method: Applied to seeds on-farm at time of planting (> 90% of total lbs used), and applied to seeds in commercial seed treatment facilities.

Maximum Rate: Applied to seed at 0.03125 (oats) to 0.125 (corn) lbs ai per 100 lbs of seed. When planted, 0.00425 (sorghum) to 0.0512 (wheat) lbs ai/acre (A) based on 6.76 lbs seed/A for sorghum and 120 lbs seed/A for wheat. For the pending registration on canola, the rates are 1.5 lb ai/100 lbs seed or 0.12 lbs ai/A based on 8 lbs seed/A.

Timing: Once in spring (or fall for winter wheat) at time of planting.

D. Estimated Usage of Pesticide

Table 1 summarizes the best estimates available for the pesticide uses of lindane, based on available pesticide usage information for 1996 to 2001. A full listing of all uses of lindane with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket and on the internet at http://www.epa.gov/pesticides/reregistration/lindane. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Up to 233,000 lbs ai of lindane are used annually for seed treatment, which accounts for all of lindane used in the U.S., according to Agency and registrant estimates. Seed treatment use of lindane has decreased over the years. In 1977, up to 937,000 lbs ai were use, of which approximately 48% or 450,000 lbs ai were used for seed treatment.

Table 1. Lindane Estimated Usage for All Sites

Crop	Acres Crop Grown	Lbs. Active Ingredient Applied		Percent Crop Treated	
		Wt. Avg.[1]	Likely Maximum	Wt. Avg.	Likely Maximum
Barley/wheat	68,373,000	89,422	153,294	7%	12%
Corn	79,545,000	51,545	77,318	6%	9%
Oats/rye	5,812,000	843	1,685	1%	2%
Sorghum	9,195,000	331	662	1%	2%
Totals		142,141	232,959		

[1] Weighted Average is based on data for 1996 - 2001; the most recent years and more reliable data are weighted more heavily.

III. Summary of Lindane Risk Assessments

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organochlorine pesticide lindane, as fully presented in the following documents:

Human Health Risks

- *Revised HED Risk Assessment for Lindane*, dated July 31, 2002
- *Revised Assessment of Risk from Use of Lindane for Treatment of Lice and Scabies*, dated July 31, 2002
- *Revised Estimates of the Number of Acres Treated per Day for Lindane Seed Treatment Use of Field Corn*, dated June 26, 2002

Environmental Fate and Effects

- *Revised EFED RED Chapter for Lindane*, dated July 31, 2002
- *Addition of corn and canola seeds treatment use to revised Lindane RED,* dated June 17, 2002
- *Lindane Food Chain Bio-Accumulation, -Magnification and -Concentration,* dated June 17, 2002
- *Qualitative Assessment of Long-range Transport and Atmospheric Deposition of Lindane to Great Lakes*, dated June 17, 2002

The listed documents may be found on the internet at http://www.epa.gov/pesticides/reregistration/lindane and in the OPP public docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, and is open Monday through Friday, excluding legal holidays from 8:30 am to 4:00 pm.

EPA issued its preliminary risk assessments for lindane in the public docket and on the internet on August 29, 2001. In response to comments and studies submitted to the Agency, the risk assessments were updated and refined. These risk assessments were made available to the public a second time on January 31, 2002, for comment on risk management for this pesticide. There is a discussion of these comments in Section IV, later in this document. The risk assessments presented here form the basis of the Agency's risk management decision for lindane.

A. Human Health Risk Assessment

The human health risk assessment for pesticides is conducted on exposures that may result from food, drinking water and non-occupational use. A separate occupational risk assessment is conducted for farmers and other professional pesticide handlers or applicators. Although there are no residential (e.g., home gardens and lawns) or other non-occupational (e.g., golf course) pesticidal uses of lindane registered by EPA, lindane is approved by FDA for the treatment of head lice and scabies on humans.

EPA has also conducted an assessment of the risks resulting from exposure to lindane. The risk assessment considered the exposure received by the general population and major identifiable subpopulations, both from the use of lindane in registered pesticide products and from use of lindane in pharmaceutical products. The use of lindane in registered pesticide products comprise applications of lindane to seeds of various commodities for purposes of insect control, and this use results in human exposure via residues in food and drinking water. The approved pharmaceutical uses and products for control of head lice and scabies, which are regulated by FDA, results in direct human exposure and via residues in drinking water. The conclusions of the risk assessment are summarized below.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is essentially complete to support a reregistration eligibility determination for all currently registered uses of lindane. Lindane primarily affects the nervous system. In acute, subchronic, and developmental neurotoxicity studies and chronic toxicity/oncogenicity studies, lindane was found to cause neurotoxic effects. Lindane also appears to cause renal and hepatic toxicity. In addition, there is some evidence that lindane may act as an endocrine disruptor; however, further investigation is necessary to ascertain the relevance and impact of such findings on public health.

EPA has not received adequate data to determine if there are any lindane metabolites of toxicological concern in plants. Historically only lindane *per se* has been analyzed; hence, none of its metabolites have been considered when assessing exposure from eating treated crops. The Agency has received some metabolism studies to determine the type of residues that may be available from crops treated with lindane as a seed treatment, and feeding studies in which livestock were orally dosed with lindane. However, additional metabolism data are needed to determine whether there are metabolites of toxicological concern in plants. To account for the undetermined, but potential toxic effects from lindane metabolites in plants, total radioactive residues (TRRs) were used for risk assessment purposes, and all metabolites of lindane are considered equally toxic to lindane, *per se*.

As noted previously, lindane has historically been classified as a B2/C carcinogen and the Agency has regulated it as a class C carcinogen pending receipt of additional studies. In 2001, the Agency reevaluated the carcinogenicity of lindane, in which all the available information/data were considered including a newly submitted carcinogenicity study in CD-1 mice. In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July 1999), the Agency classified lindane as "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." This classification was based on an increased incidence of benign lung tumors in female mice only. Therefore, pursuant to the cancer guidelines, quantification of cancer risk is not required.

Further details of the toxicity of lindane can be found in the July 31, 2002 *Revised HED Risk Assessment for Lindane*. A brief overview of the toxicological studies used for the dietary risk assessment and other relevant information is outlined in Table 2.

b. Reference Dose and Uncertainty Factor

The acute Reference Dose (aRfD) or chronic RfD (cRfD) is the no-observed-adverse-effect-level (NOAEL) divided by an uncertainty factor (UF), and is the dose at which an individual could be exposed with no expected adverse health effects. The aRfD is applicable to single day exposures, while the cRfD is applicable to lifetime exposures. The UF for lindane is 100X, based on 10X for interspecies extrapolation (from animals to humans) and 10X for intraspecies variability (based on human variability).

c. FQPA Safety Factor

FQPA provides an additional tenfold (10X) special safety factor in assessing the risks to infants and children to take into account the potential for pre- and postnatal toxicity, and the completeness of the toxicity and exposure databases. This is referred to as the FQPA Safety Factor (SF). The statute authorized EPA to reduce or remove this default 10X FQPA SF only if, based on reliable data, the resulting margin would be safe for infants and children.

There was evidence of a qualitative increase in susceptibility in the rat multi-generation reproduction study, and a quantitative increase in susceptibility demonstrated in the rat developmental neurotoxicity study. The offspring effects seen in the developmental neurotoxicity study were the same as those seen in the two-generation reproduction study. No additional functional or morphological hazards to the nervous system were noted. However, the data provided no indication of quantitative or qualitative increased susceptibility/sensitivity in rats following *in utero* exposure to lindane in the prenatal developmental toxicity studies in rats, because the developmental effects were observed only at or above doses causing maternal toxicity.

The Agency concluded that a reduced FQPA SF is required for lindane, since there is evidence of increased susceptibility of the young demonstrated in both the developmental neurotoxicity study (quantitative difference of approximately 3X) and the 2-generation reproduction study in rats (qualitative). The FQPA SF was reduced to 3X, because: 1) the toxicology data base is complete; 2) the available data provide no indication of quantitative or qualitative increased susceptibility in rats from *in utero* exposure to lindane in the prenatal developmental study; 3) the offspring effects seen in the developmental neurotoxicity study were the same as those seen in the two-generation reproduction study (no additional functional or morphological hazards to the nervous system were noted); 4) adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess food exposure and to provide a screening-level drinking water exposure assessment; and 5) there are currently no residential uses of lindane. The FQPA SF of 3X for lindane is applicable to all population subgroups for acute and chronic dietary risk assessments.

d. Population Adjusted Dose (PAD)

The Population Adjusted Dose (PAD) is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA SF (i.e., RfD ÷ FQPA SF). In the case of lindane, the FQPA SF is 3X, therefore the acute PAD (aPAD) and chronic PAD (cPAD) reflect the acute and chronic RfDs divided by the FQPA SF of 3X. An exposure estimate that is less than 100% of the acute or chronic PAD is not of concern to the Agency. Table 2 presents the PADs used to assess lindane acute and chronic dietary exposure.

Table 2. Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Lindane

Assessment	Dose (mg/kg/day)	Endpoint	Study	UF & FQPA SF	PAD (mg/kg/day)
Acute Dietary	NOAEL= 6	Increased grip strength, decrease grooming behavior and motor activity at 20 mg/kg/day (LOAEL).	Rat Acute Neurotoxicity	100 & 3	0.02
Chronic Dietary	NOAEL = 0.47	Periacinar hepatocyte hypertrophy, increased liver/spleen weight, decreased platelets at 4.81 mg/kg/day (LOAEL).	Chronic Feeding and Carcinogenicity in Rats	100 & 3	0.0016

NOAEL= No-observed-adverse-effect level
LOAEL= Lowest-observed-adverse-effect level

e. Exposure Assumptions

The dietary assessment evaluates the pre-plant seed treatment uses on barley, corn, oats, rye, sorghum, and wheat, which are the only food/feed uses of lindane being supported for reregistration. Additionally, this risk assessment also includes the pending new registration of pre-plant seed treatment of lindane on canola for informational purposes. The decision on whether or not to register canola as a new use is outside the scope of this RED and will be made separately by the Agency.

U.S. General Population

The acute and chronic dietary exposure analyses for lindane were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-92. For the acute dietary risk assessment, the entire distribution of single day food consumption events was combined with a distribution of residues to create a distribution of exposure in mg/kg/day. This is known as a probabilistic analysis. Risk is reported at the 99.9^{th} percentile of exposure.

For the chronic dietary risk assessment, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

Existing data from radiolabeled studies indicate uptake of residues from treated seeds into the aerial portion of the growing plant. In the absence of acceptable metabolism studies, the Agency concluded that the total radioactive residues (TRRs) should be used for risk assessment purposes until adequate plant metabolism studies are submitted. For lindane, the acute and chronic dietary analyses were conducted using anticipated residues for all commodities supported for reregistration, and the pending new use on canola. These analyses included percent crop treated information (listed in Table 1 for registered uses and 10% crop treated for canola use); TRRs from seed treatment, poultry and ruminant metabolism studies; and a canola processing study. The canola processing study found no detectable lindane residues in canola oil; therefore, one-half the limit of quantitation (½ LOQ) was used as the average residue.

Special Populations

Lindane does not occur naturally in the environment. Once released into the environment, lindane can partition into all environmental media. Because of long-range atmospheric transport, lindane has been detected in air, surface water, groundwater, sediment, soil, ice, snowpack, fish, wildlife, and humans. The Arctic is considered a "sink" for persistent organic pollutants, such as lindane, because they become less volatile in colder regions and are deposited. Once in the Arctic, lindane bioconcentrates rapidly in microorganisms, invertebrates, fish, birds and mammals, especially in fat tissue. However, although lindane may bioconcentrate rapidly, most data suggest that biotransformation and elimination are relatively rapid once exposure is discontinued.

The indigenous peoples of the Arctic region of the U.S. (Alaska) rely heavily on game as a food source. Because lindane can concentrate in game, the Agency performed a supplementary chronic dietary exposure and risk assessment for indigenous Alaskan people from subsistence diets to determine the risk from the worldwide manufacture and use of lindane. An acute dietary exposure assessment is not possible at this time, because the Agency does not have the information on a typical day's diet of indigenous Alaskan people.

The chronic dietary assessment was based on annual harvest rates of game obtained from the Alaska Department of Fish and Game Division of Subsistence for 1990-2001. These annual harvest rates were then divided by 365 to obtain daily harvest rates, which were conservatively assumed to be equivalent to daily intake rates. In addition, the Agency used total hexachloro-cyclohexane (HCH) residues in traditional foods, based on information provided by Dr. Laurie Chan of McGill University in Canada, with adjustments to estimate lindane exposure because lindane represents between 3 and 15% of total HCH residues in game. This assessment evaluated the three highest exposed communities of approximately 180 Alaskan communities with the highest harvest amounts of seal, whale, and walrus. For this assessment, the Agency's evaluation only covers adult males, adult females, and children 1- 6 and 7 - 12 years old, because there are insufficient data to assess other age groups.

f. Food Risk Assessment

The dietary (food) assessment was conducted using percent crop treated (%CT) information and TRR from various metabolism studies. The acute dietary (food) exposure analysis is a highly refined Tier 3 probabilistic assessment, and exposure was compared to the aPAD. In the deterministic chronic dietary assessment, exposure was compared to the cPAD. As noted previously, dietary risk estimates less than 100% of the aPAD or cPAD do not pose risks of concern to the Agency. More information on the dietary (food) risk assessment for lindane is available in the *Revised HED Risk Assessment for Lindane*, dated July 31, 2002.

U.S. General Population

For the U.S. population, the lindane acute dietary exposure estimates at the 99.9th percentile are below 100% of the aPAD for all population subgroups. The subgroup with the highest estimated exposure (infants <1 years) resulted in an estimated exposure of 17% of the aPAD. The general U.S. population's acute dietary exposure is 7% of the aPAD.

Average chronic dietary exposure estimates are below 100% of the cPAD for all populations subgroups usually considered. The subgroup with the highest estimated exposure (children 1-6 years) resulted in an estimated average exposure of 11% of the cPAD. The general U.S. population's average chronic dietary exposure is 3% of the cPAD. The acute and chronic dietary exposures and risks are presented on Table 3.

Table 3. Estimated Acute and Chronic Dietary Exposures and Risks

Population Subgroup	Acute (99.9th %-ile)		Chronic (average exposure)	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.001305	7	0.000054	3
All infants (<1 yr)	0.003320	17	0.000072	5
Children (1-6 yrs)	0.001973	10	0.000173	11

Special Populations

As noted previously, an acute dietary assessment for indigenous people is not possible at this time because the Agency does not have the information on a typical day's diet. Nevertheless, based on limited residue data, the Agency believes acute dietary risks are unlikely to be of concern because indigenous adults and children would have to consume more than 50 lbs and 10 lbs, respectively, of game in a single day containing the maximum detected lindane residues to exceed the aPAD.

The chronic dietary risks based on consumption of traditional foods are generally not of concern. For the most highly exposed subpopulation, children 1 - 6 years, the subsistence diet of Alaskans results in lindane exposures that range from 13 - 65% of the cPAD, with the exception of one scenario which was 138% of the cPAD. This exception was for one community where EPA included a number of conservative assumptions discussed below, including that children ate blubber for 365 days/year for six years. For the adult population, the subsistence diet is 3 - 44% of the cPAD. The estimated chronic dietary exposure and risk estimates for the indigenous people of Alaska are presented in Table 4.

Table 4. Assumed Total Dietary Intake of Lindane (gamma-HCH) and Estimated Chronic Dietary Risk for Indigenous Peoples

Population Subgroup	Body Weight (kg)	Lindane Exposure (mg/kg/day)	% cPAD
Adult male	70	0.000055 - 0.0006	3 - 38
Adult female	60	0.000064 - 0.00071	4 - 44
Children (7-12 years)	29	0.00007-0.0008	4 - 48
Children (1-6 years)	10	0.0002 - 0.001, 0.0022	13 - 65, 138

For the chronic dietary risk to indigenous populations in Alaska, the Agency believes this assessment is conservative and probably overestimates dietary risk because:

(12) this assessment is based on the three communities with the highest dietary exposure (highest harvest amounts of seal, whale, and walrus) of the approximately 180 Alaskan communities surveyed;
(13) maximum detected residues in any game tissue were used to assess chronic exposure;
(14) whale, walrus and seal blubber residues were used to assess all meat residues, which are expected to have much lower lindane residues than blubber;
(15) it was assumed that harvest was equal to intake (i.e., adults consume up to 2.4 lbs and children up to 1.3 lbs of meat per day); and
(16) children's consumption is based on data from the diet of 7 - 12 year-olds while the risk assessment assumes the same amount is eaten for 1 - 6 year-olds.

2. Drinking Water Concentrations from Agricultural Uses

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks. The Agency uses a tiered system of exposure modeling, and, if available, monitoring data to estimate those risks. Each of the tiers are designed to screen out pesticides by requiring higher, more complex levels of investigation for those that have not passed the next lower tier. For lindane, Tier I drinking water models were used, which are considered to be preliminary assessments and provide high-end estimates of exposure. Although monitoring data are available

for lindane, this assessment relies on modeling estimates, because monitoring data were randomly collected and not correlated with any particular use pattern. Additionally, information on the site characteristics within the monitored basins would be necessary to understand the relative vulnerability of the recipient surface waters. Moreover, the monitoring data collected reflect many uses of lindane that have since been cancelled, and therefore, do not reflect the current use pattern.

Lindane is persistent and moderately mobile, with an estimated aerobic soil half-life of 2.6 years. It is resistant to photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial action. Lindane degrades predominantly to isomers of benzene hexachloride, pentachlorocyclohexane, 1,2,4-trichlorobenzene, and 1,2,3-trichlorobenzene at low concentrations (less than 10% of the total residues); therefore, these degradates were not quantified for use in the drinking water assessment.

Lindane is transported through the environment by both hydrologic and atmospheric means. Lindane has often been detected in surface and ground water, and in areas of non-use (e.g., the Arctic), indicating long-range atmospheric transport. Most of these detections have likely resulted from a combination of lindane's past widespread use, long-range transport, and its extreme persistence. Currently, U.S. agricultural uses of lindane are restricted to seed treatments, and application rates are quite low. However, it is conceivable that a certain level of lindane may continue to persist in non-use areas despite the limited use of lindane to treat seed. Additional details of the physical-chemical properties of lindane are discussed in the *Revised EFED RED Chapter for Lindane,* dated July 31, 2002.

a. Modeling Data

Exposure from Surface Water

Drinking water estimated concentrations (DWECs) from surface water sources were derived from the FQPA Index Reservoir Screening Tool (FIRST) model, which is based upon the linked Pesticide Root Zone Model (PRZM) and Exposure Analysis Modeling System (EXAMS) models, and includes use of an Index Reservoir. FIRST is a Tier I screening-level model designed to provide high-end estimates of potential pesticide exposure in surface water sources of drinking water. The estimated peak (acute) and chronic (average) DWECs from surface water sources are listed in Table 5 for the highest planted seed treatment rate for the supported uses (wheat at 0.051 lb ai/A), and for the proposed new use on canola (0.116 lb ai/A).

Exposure from Ground Water

The Agency used the Screening Concentration in Ground Water (SCI-GROW) model, which is a Tier I screening-level model to estimate concentrations of lindane in ground water. The estimated DWEC from ground water sources is listed in Table 5 for the highest planted seed treatment rate for the supported uses (wheat at 0.051 lb ai/A), and for the proposed new use on canola (0.116 lb ai/A).

Table 5. DWECs of Lindane in Drinking Water

Drinking Water Source	Crop	Acute DWEC (ppb)	Chronic DWEC (ppb)
Surface Water	wheat	0.98	0.46
	canola	4.16	1.95
Ground Water	wheat	0.011	0.011
	canola	0.025	0.025

b. Monitoring Data

For ground water, the U.S. EPA STORET data base reported 720 detections of lindane between the years 1968 and 1995, in nearly all regions of the country, with especially high numbers of detections in the South and West. From these 720 detections, the median and mean concentrations were 0.01 and 11 ppb, respectively. The maximum detected concentrations were reported in two wells at a Superfund site in Alabama (5800 and 1000 ppb) in 1982 and 1984, and appear to be outliers because subsequent sampling of these wells in 1985 showed much lower lindane concentrations of 2.5 ppb. The next highest lindane concentration was 120 ppb in 1982 from a well in Alabama. All other concentrations are less than 10 ppb. In the USGS NAWQA ground water database, lindane was detected in 0.1 % of ground water samples (0.07% at levels greater than 0.01 ppb, maximum concentration reported was 0.032 ppb).

For surface water, the U.S. EPA STORET data base reported 8775 detections of lindane with median and mean concentrations of 0.005 and 0.18 ppb, respectively. STORET detections were reported in nearly all regions of the contiguous U.S. In the USGS NAWQA study, lindane was detected in 2.58% of surface water samples (0.67% at levels greater than 0.05 ppb, maximum concentration reported was 0.13 ppb).

Although these long-term monitoring data have detected lindane in various water bodies, the Agency determined that these data are not suitable for risk assessment purposes for the reasons discussed earlier, and are presented here solely for informational purposes. Nevertheless, the mean and median concentrations from monitoring data, as well as the maximum detected concentrations are low and not of concern, with the exception of the two samples collected near a Superfund site in Alabama in ground water nearly 20 years ago. Subsequent sampling of these wells showed levels of 2.5 ppb, which would not pose levels of concern. As noted earlier, the monitoring data collected include many uses of lindane uses that have since been cancelled, and therefore, does not reflect the current supported seed treatment uses alone. However, even though many uses of lindane have since been cancelled, modeling indicates that the seed treatment uses of lindane can result in measurable concentrations of lindane in drinking water sources.

3. Risk from Pharmaceutical Uses

Lindane is also available, and regulated by FDA, for the treatment of scabies and head lice. A 1% lindane lotion is available for the treatment of scabies, and a 1% lindane shampoo is available for the treatment of head lice. The products are available by prescription only, with use intended as a second line therapy for the treatment of patients who have either failed to respond to, or are intolerant of, other approved therapies. It is currently supplied by the manufacturer in a 2-ounce patient size bottle, and a pharmacy-only size pint bottle. EPA's current understanding of available data regarding the use of lindane pharmaceutical uses is present in the *Revised Assessment of Risk from Use of Lindane for Treatment of Lice and Scabies*, dated July 25, 2002.

a. Scabies Treatment

The Agency performed two risk assessments for use of lindane to treat scabies uses. Data were utilized from both animal and human studies, and a range of risk estimates is provided. EPA conducted analyses using: 1) a Margin of Exposure (MOE) approach based on an animal toxicity study; and 2) a comparison of lindane blood levels from one study which documents cases of accidental lindane ingestion by toddlers in which blood levels were determined after ingestion, and a second study which provides data on blood levels of lindane in children and young adults following application of lindane to treat scabies. The first assessment (MOE approach) followed conventional risk assessment methodologies and relied on animal data, and the second assessment was performed using human blood levels.

MOE Approach

Risk Assessment

An estimated MOE is calculated based on a selected toxicological endpoint and compared with the target MOE for short-term dermal exposure/risk to determine whether there is an exposure of concern. The MOE is the ratio of the route appropriate NOAEL to estimated exposure. For the short-term dermal endpoint for lindane, the Agency used a NOAEL of 6 mg/kg/day from an acute oral neurotoxicity study in rats. For non-occupational exposures, uncertainty factors are used to determine target MOEs. The target MOE for non-occupational exposures to lindane is 100, based on uncertainty factors (UF) used to account for differences among humans (10X UF for intraspecies variability), and for differences between the test animals and humans (10X for interspecies extrapolation).

Since the NOAEL is based on an oral toxicity study, dermal absorption data are required to adjust the oral dose. Based on published articles, two different dermal absorption factors were used to calculate estimated MOEs. One article reported data from a dermal absorption study conducted on rhesus monkeys to determine if 1% lindane lotion applied for treatment of lice and scabies is absorbed into the blood stream. Results from the study demonstrated that a weighted average of 20% of the applied dose was absorbed following application to various regions of the body. A second dermal absorption factor was taken from a study in which a lindane pesticide

formulation was applied to human subjects to quantify dermal penetration. From this study, lindane was shown to have a penetration factor of about 10%.

Results of the scabies MOE assessment for children and young adults using both monkey and human dermal absorption data using conventional animal toxicity studies are provided in Table 6. The analysis indicates MOEs of concern (MOE<100) from both high and low-end treatment scenarios. The monkey assessment assumes that doses are applied at rates prescribed on the label.

Table 6. Assessment of Scabies Use

Age Group	Applied Dose (mg)	Daily Dermal Dose (mg/kg/day)	Dermal Absorption (%)	MOE [a,b]
Dermal Absorption Factor from Product Specific Monkey Study				
Young Adult	600 high end	10	20	3
Young Adult	300 low end	5	20	6
Child (4-6 years)	300 high end	11	20	3
Child (4-6 years)	150 low end	7	20	4
Toddler (1-3 years)	300 high end	15	20	2
Toddler (1-3 years)	100 low end	8	20	4
Dermal Absorption Factor from Pesticide Exposure in Human Study				
Young Adult	600 high end	10	10	6
Young Adult	300 low end	5	10	12
Child (4-6 years)	300 high end	11	10	5
Child (4-6 years)	150 low end	7	10	9
Toddler (1-3 years)	300 high end	15	10	4
Toddler (1-3 years)	100 low end	8	10	8

[a] Does not include an FQPA Safety Factor which, if applied, would increase the target MOE to 300 for infants and children.
[b] Target MOE is 100

Uncertainties with MOE Risk Assessment

The toxicity endpoint used in the MOE assessment is based on an acute oral neurotoxicity study where the test material was administered by gavage. An oral gavage dose may be absorbed more rapidly than the dermal dose, thus use of a toxicity endpoint based on an oral dose may overestimate toxicity from a dermal dose. Furthermore, since adult animals were used in the acute

oral study and children are more susceptible to exposure than adults, use of a toxicity endpoint based on the acute study may underestimate risks to children who are exposed to lindane.

EPA calculated MOEs using different dermal absorption factors. The 20% absorption value derived from the scabies lotion applied to monkeys may be an overestimate of dermal absorption, because it was left on longer (24 hours) than label instructions (12 hours). In addition, since there are no data to evaluate the relative absorption of the scabies lotion by monkeys vs. humans or the relative absorption by humans of the pesticide vs. scabies lotion, it is not possible to assess whether these dermal absorption factors tend to overstate or understate potential risk. However, use of both studies provides a range of dermal absorption and probably provides an adequate bounding of potential exposure.

EPA conducted its MOE assessment for scabies treatment to toddlers (1-3 years) and children (years 4-6 years), in accordance with directions provided in the current label. According to the FDA, the label for the 1% scabies treatment lotion will be revised to restrict use to "patients who have attained adult stature, or approximately 60 kg" and to recommend only that a thin layer of lotion be applied. Given anticipated label changes, use in accordance with the revised label would eliminate risks to young children (less than 60 kg). Also, according to FDA, pending label changes to the amount of lotion required should result in lower application rates for both older children and adults.

Blood Level Comparison in Children

Risk Assessment

EPA also analyzed potential risk from lindane used as a scabies treatment based on data on lindane blood levels provided in two published case reports. One study documents cases of accidental lindane ingestion by toddlers in which blood levels were determined after ingestion. The second study provides data on blood levels of lindane in children after application of 1% lindane lotion to treat scabies. The blood level associated with acute accidental ingestion of the contents of a bottle of Kwell (lindane) lotion, which resulted in short-term adverse effects according to the accidental ingestion case study, is 0.32 μg/mL. Furthermore, the Physicians Desk Reference (PDR) provides the following statement on clinical pharmacology regarding 1% lindane cream, "Dale, et al reported a blood level of 290 ng/ml [0.29 μg/mL] associated with convulsions following the accidental ingestion of a lindane containing product."

EPA also has a published study on blood levels of lindane in infants and children who had received scabies treatment with 1% lindane lotion. In this study, serum concentrations of lindane were determined in infants and children with and without scabies infection following application of 1% lindane lotion to the body surface area as prescribed by the label. Studies were performed on 20 infected and noninfected patients who averaged 33 to 64 months of age. The current label for lindane lotion applied for scabies specifies that the lotion should not be left on for more than 12 hours. Specimens of blood for determination of lindane concentrations were obtained at 0, 2, 4, 6, 8, 12, 24, and 48 hours after topical application of 1% lotion. The highest measured blood concentration from the clinical study was 0.064 μg/mL. Results are presented in Table 7.

Table 7. Blood Concentrations of Lindane After Scabies Treatment

Mean Concentrations of Lindane in Blood (μg/mL)				
Time (hr)	Infected		Noninfected	
	Avg	Range	Avg	Range
2	0.013	0.005-0.038	0.007	0.001-0.017
4	0.025	0.007-0.048	0.013	0.008-0.027
6	0.028	0.013-0.039	0.024	0.007-0.064
8	0.026	0.010-0.037	0.019	0.009-0.040
12	0.023	0.002-0.043	0.015	0.002-0.033
24	0.010	0.003-0.019	0.013	0.006-0.024
36	0.008	0.002-0.012	0.009	0.004-0.018
48	0.006	0.001-0.021	0.005	0.002-0.008
Blood half-life	17.9 hr		21.4 hr	

Uncertainties with Blood Level Analysis

It is uncertain whether the levels of 0.32 μg/mL represent the maximum levels of lindane in the subjects' blood. Given that the measured level of 0.32 μg/mL in the cited clinical study was taken at least 4 hours after ingestion, it is likely that initial blood levels were higher. It is also uncertain what blood level is associated with the effects observed in the case study patient, thus to the extent that observed effects are attributable to higher or lower than measured lindane blood levels, the assessment may tend to overestimate or underestimate risk, respectively. In addition, the subjects in the clinical study received a bath with warm soapy water prior to application of the lindane lotion. Wet skin tends to exhibit greater dermal absorption than dry skin; hence, use of the blood levels from the study may overstate potential exposure for individuals who have dry skin at the time of application.

In the clinical study, the lindane lotion was left on for 24 hours after application. The current label for scabies treatment specifies that the lotion should not be left on for more than 12 hours. Although this prolonged exposure may result in an overestimation of blood concentrations seen after 12 hours, it should not effect the 6 hour peak level used in the risk assessment. Additionally, the potential contribution of other lotion components to observed effects is not known.

Based on the average age, the clinical scabies study included only infants and small children (up to 8 yrs old). Average amounts of lindane applied in the study were 2-4 times less that prescribed on the current label. However, the label for the 1% scabies lotion is to be revised by FDA to prohibit use of the product for small children (i.e., children less than 60 kg), thus use in

accordance with the revised label would eliminate risks to young children (<60 kg). Also, according to FDA, pending label changes on the amount of lotion required should result in lower application rates for both older children and adults. Although there is insufficient data to indicate a correlation between amount applied dermally and corresponding blood levels, it is reasonable to assume that use of a lower amount of product will produce lower lindane blood levels. Finally, the new label will direct that lindane be applied to dry skin, which will reduce the amount of lindane absorbed into the blood stream.

The blood level comparison analysis pertains and is applicable only to small children. The Agency has no data on blood levels associated with adverse effects in adults or data on blood levels associated with prescribed use of lindane to treat scabies in adults. Based on available toxicity data, children are more sensitive than adults; therefore, adverse effects would occur at higher blood levels in adults and older children than in young children. In addition, blood levels associated with prescribed use (under both current and revised labels) would be lower in older children and adults, due to differences in weight to body surface area ratios between young children and adults/young adults.

Scabies Treatment Risk Conclusion

EPA's analysis using the animal data MOE approach indicates MOEs of concern from both high and low-end treatment scenarios for all ages assessed using either monkey or human dermal absorption data. For the blood concentration analysis, EPA compared adjusted blood concentrations from the scabies study with blood concentration associated with short-term adverse effects in children. Given variability of responses in humans, an uncertainty factor of 10 is considered reasonable for this risk assessment. There is a 4-5 fold difference between blood levels in treated patients and allowable blood levels identified, based on evidence of adverse effects. While this assessment considers mitigation efforts being taken by FDA, it is important to note that it does not consider the medical benefits of scabies treatment.

b. Lice Treatment

The Agency's assessment of risk from use of lindane to treat head lice relies on data provided in two published literature studies. One study documents cases of accidental lindane ingestion by toddlers in which blood levels were determined after ingestion, and was discussed above as part of the scabies treatment assessment. The second study provides data on blood levels of lindane in children and young adults following application of Kwell (lindane) shampoo to treat head lice.

In the head lice Kwell shampoo study, serum concentrations of lindane were determined in children with pediculosis capititis following application of 1% Kwell shampoo. Studies were performed in 9 patients who were from 3.5 to 18 years of age. After a pretreatment blood sample was obtained, 1% lindane product was applied to dry hair using a sufficient amount of medication to thoroughly saturate the hair and scalp. After 10 minutes, small quantities of water were added until a lather formed. Shampooing was continued for an additional 4 minutes after which the hair

was rinsed and blown dry with a hair dryer. The current label for lindane shampoo specifies that the shampoo should remain in place on dry hair for 4 minutes only before water is added to form lather. Consequently, the study may have resulted in higher absorption than would occur following label directions. Four patients were retreated, because of persistence of living lice after 5 days. Specimens of blood were obtained at 0, 2, 4, 6, and 24 hours after topical application of Kwell shampoo. The results are presented in Table 8.

Table 8. Blood Concentrations of Lindane After Lice Treatment

Mean Concentrations of Lindane in Blood (μg/mL)				
Time (hr)	Initial Treatment		Retreatment	
	Avg	Range	Avg	Range
0	0		0.00029	0.00025-0.0003
2	0.0014	0.00043-0.00253	0.0036	0.00326-0.00388
4	0.00096	0.00038-0.00152	0.0033	0.00175-0.00613
6	0.00072	0.00029-0.00105	0.0021	0.00164-0.00264
24	0.00041	0.00026-0.00069	0.0011	0.00081-0.00133

Uncertainties with Blood Level Analysis

Likewise to uncertainties associated with the blood level analysis of scabies treatment, it is uncertain whether the level of 0.32 μg/mL represent the maximum levels of lindane in the subjects' blood, and what blood level is associated with the effects observed in the case study patient. Thus, to the extent that observed effects are attributable to higher or lower than measured lindane blood levels, the assessment may tend to overestimate or underestimate risk, respectively. Moreover, the current label for lindane shampoo specifies that the shampoo should remain in place on dry hair for 4 minutes only before water is added to form lather. In the clinical study, the shampoo was left in place for 10 minutes before water was added. Consequently, the study may result in higher absorption than would occur following label directions.

Lice Treatment Risk Conclusion

The highest measured blood concentration obtained following single and double treatments of head lice at label rates, but at longer than label specified treatment durations, was 0.00613 μg/mL. This is significantly lower than 0.32 μg/mL, the blood level associated with acute accidental ingestion, which resulted in short-term adverse effects according to the cited case study article. Therefore, the Agency does not believe that lindane pharmaceutical products used for treatment of lice pose acute human health risks of concern when used in accordance with directions provided on the label.

c. Drinking Water Concentrations from Pharmaceutical Uses

The Agency also assessed the risks associated with estimated concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies treatments. The "down-the-drain" releases assessment is based on an Agency exposure model, Exposure and Fate Assessment Screening Tool (E-FAST). Surface water concentrations were based on the reported lindane concentration of discharged effluent from the Publically Owned Treatment Works (POTWs) of Sanitation Districts of Los Angeles County, California. The reported median concentration of lindane ranged from 0.01 to 0.04 ppb. These concentrations were averaged (0.03 ppb) and used in estimating surface water concentrations.

As part of this assessment, the Agency assumed that the reported concentration of lindane from wastewater treatment was discharged and instantaneously diluted into surface water where no further removal (e.g., degradation, absorption, volatilization) occurs. Also, different stream dilution factors, which are the volume of receiving stream flow compared with the volume of wastewater released from the POTW, were assumed to estimate acute and chronic DWECs from surface water sources. Based on these data and assumptions for pharmaceutical use only of lindane, the acute DWEC is 3.97×10^{-4} ppb and the chronic DWEC is 3.06×10^{-5} ppb. The Agency believes that a conservative approach was used to estimate acute and chronic DWECs, because of the instantaneous and upper-end stream dilution factors that were assumed in the assessment.

d. Spontaneous Adverse Event Reports

Based on information provided by FDA, the most common adverse events from the pharmaceutical uses of lindane (topical treatment) are skin irritation, and central nervous system stimulation ranging from dizziness to seizures. The majority of adverse events occurred because of misuse of the product, either ingestion or excessive topical application, but some have occurred when the product was apparently used as recommended.

A postmarketing safety review conducted by FDA revealed 488 reports of adverse events related to the use of lindane in the Adverse Event Reporting System (AERS) database as of April 1, 2002. Spontaneously submitted reports are not considered incidence data since the total number of patients treated with lindane is unknown, and the actual number of associated adverse events is under reported. The AERS database reports included: outcome of death (15), hospitalization (46), life threatening condition (7), and congenital anomaly (6). Only sixteen of these cases occurred with lindane shampoo, and four of the sixteen were oral ingestion.

There were fifteen deaths, nine in adults and five in children, and one stillborn infant possibly exposed during pregnancy. Of the cases where the route of administration could be determined, thirteen of the patients were treated topically and one patient ingested lindane to commit suicide. Two adult cases reported serious preexisting conditions, and four were elderly. Three of the elderly patients died within 24 hours of treatment, one from pulmonary edema, one from chronic obstructive pulmonary disease, and the third of the unreported condition. A fourth elderly patient suffered a seizure on the day of death, 41 days after treatment with lindane. Three of the four elderly patients had contraindications to the use of lindane.

Three of the pediatric deaths were secondary to the other causes, including respiratory syncytial virus infection, myelocytic leukemia, and lymphoma of the brain. The fourth pediatric case involved a fetus that may have been exposed *in utero* and was stillborn. The adverse event report form stated that application occurred up to four times over four days. This would suggest that the child received multiple treatments on consecutive days. FDA has concluded that in all age groups, adverse events occurred mainly in patients who appeared to have misapplied or ingested lindane.

One of the limitations of a voluntary system of reporting, such as for AERS, is the substantial amount of under-reporting. The FDA estimates that 1-10% of all adverse events are reported to the FDA. Other limitations include the variability in the quality and quantity of information reported. In spite of known limitations, the spontaneous system has value. The system is sensitive to rare, unexpected events, is simple to use, and is relatively inexpensive. In addition, the AERS database does not include the total number of patients who have been treated, with or without adverse events; therefore, it is not possible to quantify the percentage of patients who have had adverse events. According to FDA, most of the serious adverse events in the AERS database occurred in patients who had already labeled contraindications to the use of lindane, who used lindane in excessive amounts, or who ingested lindane.

4. Risk from All Registered Pesticide Lindane Exposures

For lindane, a risk assessment was conducted for both acute and chronic durations that considered combined food and drinking water exposures. Results of the risk assessment are summarized here and are further explained in the July 31, 2002 *Revised HED Risk Assessment for Lindane*.

To determine the maximum allowable contribution of lindane from water in the diet, the Agency first looks at how much of the overall risk is contributed by food, residential and other non-occupational sources, and then determines a drinking water level of comparison (DWLOC) to determine whether modeled or monitored water concentrations exceed this value. The Agency uses the DWLOC as a surrogate measure of risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with other sources of ambient exposure, does not exceed a level of concern. The DWLOC is then compared with the DWEC to determine whether there is a potential concern for combined exposure and risk. When the DWEC is less than the DWLOC, the Agency can make a determination of safety for combined exposures. When the DWEC is greater than the DWLOC, the Agency may not be able to make a determination of safety or may require additional data concerning potential water contamination.

Acute Risk (Food + Drinking Water)

The acute risk estimates for lindane address exposure from food and drinking water sources only, because there are no residential or other non-occupational uses of lindane that

would result in acute exposure. Acute exposure is considered to occur in a one-day time frame. Acute dietary risks less than 100% of the aPAD are not of concern to the Agency. As indicated in Table 9, the highest DWEC for the currently registered uses of lindane (wheat), resulted in 0.98 ppb for surface water and 0.011 ppb for groundwater. These DWECs are less than the acute DWLOC of 170 ppb for the most sensitive population subgroup, infants less than 1 year old. Therefore, acute risks associated with food and drinking water exposures to lindane are not of concern to the Agency.

Chronic Risk (Food + Drinking Water)

A chronic assessment estimates risk from long-term exposure to food and drinking water sources only, because there are no residential or other non-occupational uses of lindane that would result in chronic exposure. Chronic dietary risks less than 100% of the cPAD are not of concern to the Agency. As indicated in Table 9, the highest DWEC for the currently registered uses of lindane (wheat), resulted in 0.46 ppb for surface water and 0.011 ppb for ground water sources. These DWECs are less than the chronic DWLOC of 14 ppb for the most sensitive population subgroup, children 1-6 years old. Therefore, chronic risks associated with food and drinking water exposures to lindane are not of concern to the Agency.

Table 9. Summary of Food and Drinking Water Risks for Acute and Chronic Dietary Exposure

Population Subgroup	DWLOCs (ppb)		DWECs (ppb)		
	Acute	Chronic	Surface Water		Ground Water
			Acute	Chronic	
US Population	665	54	0.98 (wheat) 4.16 (canola)	0.46 (wheat) 1.95 (canola)	0.011 (wheat) 0.025 (canola)
Children (1-6 yrs)	180	14			
Infants (<1 yr)	170	15			

Special Populations (Food + Drinking Water)

For the indigenous people of the Arctic region of the U.S. (Alaska), the Agency has insufficient information on lindane concentrations in Alaskan drinking water sources to determine if exposure to lindane in food and water is of concern to the Agency. The calculated DWECs are not appropriate for assessing potential exposures in Alaska, because they are specific to seed treatment uses, and are not representative of background environmental levels of lindane in Alaska from the long-range transport of the compound. However, it is expected that the background environmental levels of lindane in Alaska are much less than the calculated chronic DWEC (0.46 ppb) for surface water sources, which represents the average concentration of lindane in a drinking water reservoir where 87% of the watershed was planted with seed treated with lindane. Drinking water monitoring data for Alaska are not available. Nevertheless, the chronic DWEC of 0.46 ppb, which is based on seed treatment use, is significantly less than the

calculated chronic DWLOC of 6 ppb for children and 31 ppb for adults. The chronic DWLOC calculations are derived from the conservative subsistence dietary food exposure estimates for all but the one Alaskan community, which resulted in 138% of the cPAD being consumed by the children (1-6 years) subpopulation. For the reasons discussed previously, the Agency believes this assessment is conservative and probably overestimates dietary risk; therefore, a chronic dietary risk in special populations does not pose a risk concern to the Agency.

As noted previously, an acute dietary assessment for indigenous people is not possible at this time, because the Agency does not have the information on a typical day's diet. Nevertheless, based on limited residue data, the Agency believes acute dietary risks are unlikely to be of concern, because of the significantly large amount of game indigenous people would have to consume in a single day to pose a risk of concern.

5. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational exposure to lindane occurs either on-farm or at commercial seed treatment facilities to farmers or workers who mix, load and/or apply lindane as a seed treatment, and persons who handle or plant treated seed. Risk for these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a NOAEL after taking into account an uncertainty factor of 100X. The uncertainty factor of 100X is based on a 10X for interspecies extrapolation and a 10X for intraspecies variability. In the case of lindane, MOEs greater than 100 for dermal and inhalation exposures are not of concern to the Agency. More information on the lindane occupational risk assessment is available in the *Revised HED Risk Assessment for Lindane*, dated July 31, 2002, and the *Revised Estimates of the Number of Acres Treated per Day for Lindane Seed Treatment Use of Field Corn*, dated June 26, 2002.

a. Toxicity

The toxicity of lindane is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for lindane. The toxicological endpoints, and other factors used in the occupational risk assessment for lindane are listed below in Table 10.

Table 10. Summary of Toxicological Information Used in the Occupational Assessment

Assessment	Dose (mg/kg/day)	Endpoint	Study
Short-and Intermediate-Term Dermal [a]	NOAEL= 1.2	Reduced pup survival, decreased body weights and body weight gains during lactation, increased motor activity, and decreased motor activity habituation at 5.6 mg/kg/day (LOAEL).	Developmental Neurotoxicity (Oral) Study in Rats
Short-Term Inhalation	NOAEL= 0.13 (0.5 mg/m^3)	Clinical signs (diarrhea, piloerection) on day 14 and continuing for 20 days at 1.3 mg/kg/day (LOAEL).	90-Day Inhalation Study in Rats
Intermediate-Term Inhalation		Increased kidney weights of females and bone marrow effects at 1.3 mg/kg/day (LOAEL).	

[a] A 10% dermal absorption factor (relative to oral absorption) was used for risk assessment.

Because an oral study was selected as the dermal toxicological endpoint for lindane, a dermal absorption factor of 10% (relative to oral absorption) was used for route-to-route extrapolation. This factor is based on a study that tested 12 pesticides, including lindane, to quantify dermal penetration. Also, the Agency believes that the offspring effects from the developmental neurotoxicity study selected to assess occupational dermal exposure are protective of all populations. Furthermore, because of the different toxicological endpoints of concern, it is not appropriate to combine the dermal and inhalation exposures as part of the occupational risk assessment.

Information in Table 11 indicates that lindane is moderately toxic following acute oral and dermal exposures, and has been placed in Acute Toxicity category II. It is not an eye or dermal irritant, or dermal sensitizer.

Table 11. Acute Toxicity of Lindane

Study Type	MRID	Category	Result
81-1 Acute oral-rat	00049330	II	LD_{50} 88 mg/kg - males 91 mg/kg - females
81-2 Acute dermal-rabbit	00109141	II	LD_{50} 1000 mg/kg - males 900 mg/kg - females
81-3 Acute inhalation-rat	Acc. 263946	III	LC_{50} 1.56 mg/L both sexes
81-4 Eye irritation-rabbit	Acc. 263946	III	no corneal involvement irritation cleared after 24 hours
81-5 Dermal irritation-rabbit	Acc. 262946	IV	not an irritant
81-6 Dermal sensitization-g. pig	Acc. 262946	NA	not a sensitizer

b. Exposure

There are potential exposures to mixers, loaders, applicators and other handlers associated with seed treatment uses of lindane. Based on the use patterns, the Agency evaluated six major worker exposure scenarios. Workers can be exposed to lindane through:

(1) on-farm seed treatment (mixing/loading/planting) with the dust formulation;

(2) on-farm seed treatment (mixing/loading/planting) with the liquid formulation using a closed transfer system;
(3) mixing/loading and applying the liquid formulation with commercial seed-treatment equipment;
(4a) seed handlers at a commercial seed treatment facility (bagger/sewer/stacker);
(4b) seed handlers at a commercial seed treatment facility (forklift operator);
(5) seed handlers at a commercial seed treatment facility (cleaner); and
(6) loading and planting treated seed.

The Agency assumed that on-farm workers could be exposed to lindane for short-term (1-30 days) durations, while commercial workers could be exposed for both short- and intermediate-term (1-6 months) durations. Several chemical-specific and surrogate chemical exposure studies were available and considered to assess worker risks; therefore, the limited data on seed treatment uses from the Pesticide Handlers Exposure Database (PHED) were not used.

On-farm seed treatment exposures with the dust formulation (scenario 1) were based on a study that monitored four workers treating wheat seed in South Dakota with a dust formulation containing 18.75% lindane (Fenske study, MRID 44405802). This study is considered to be representative of manual seed treatments in the Midwest and was used as a surrogate to assess other seed treatment as well. Dermal and respiratory exposures were measured during seed treatment activities, during which workers wore the label-required long sleeve shirt, long pants, chemical-resistant gloves, and a pesticide respirator (i.e., a half-mask, dual cartridge respirator equipped with an organic vapor cartridge and dust filter).

To assess the exposures from on-farm treatment of the liquid formulation with a closed transfer system (scenario 2) and commercial seed treatment activities with lindane (scenarios 3, 4a, 4b, and 5), the Agency considered all relevant data, including a study which was conducted at three seed-treatment plants in Alberta, Canada. This seed treatment study met guideline requirements, and was useful information because lindane was one of the active ingredients being monitored (MRID 44731501). To refine this assessment, the Agency also used surrogate data from a commercial seed treatment facility (Helix study, MRID 45200002), from which median unit dermal and inhalation exposure measurements were available to assess risks to various commercial seed treatment workers, including baggers, sewers, stackers, forklift operators, and cleaners. Because the equipment used for on-farm treatment with the liquid formulation has similar performance to the equipment used in the commercial facility, exposure data from the Helix study was also used to refine the assessment for workers treating seeds for this scenario (scenario 2). In addition, the Agency used surrogate exposure data (Isophenfos study, MRID 42251901) to assess loading and planting treated seeds (scenario 6).

Anticipated use patterns and application methods, and range of application rates were derived from current product labeling. For lindane, the Agency based its assessment on the amount of seeds that need to be treated to plant a certain number of acres in an 8 hour work day.

Because of the amount of ai applied/100 lb seed compared with the amount of seed planted/A, wheat was assessed as a representative crop for barley, oats, and rye. Similarly, corn

was assessed as a representative crop for on-farm treatment of sorghum seed with lindane. However, for occupational risks associated with commercial seed treatment practices, only wheat was assessed to represent the supported seed treatment uses, and canola was assessed for informational purposes because of the pending new use registration.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal baseline protection, and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimum to maximum levels of protection). For this assessment, worker exposures are based on the personal protective equipment (PPE) used in the chemical-specific studies and relevant commercial seed treatment studies, which are specified in Table 12.

Due to the method of seed treatment with lindane, EPA has determined that when the seeds are planted (soil incorporated), post-application agricultural exposure is considered to be negligible, as long as the soil is not directly contacted. Therefore, a post-application occupational risk assessment was not conducted.

c. Occupational Handler Risk Summary

Table 12 below summarizes the MOE values for both the short and/or intermediate-term exposure durations for the six major worker exposure scenarios, including the PPE and/or engineering controls used in the assessment. For the currently registered seed treatment uses (i.e., excluding canola), only one scenario (scenario 1; on-farm application of the dust formulation) is below the target MOE of 100 and is of concern to the Agency. Because of the rate of seeds planted per acre, the risk associated with lindane use on wheat seeds (dermal MOEs 9-17), which is representative of barley, oats, and rye, is much higher than the risk for lindane use on corn seeds (dermal MOEs 26-92), which is representative of sorghum. All other scenarios for currently registered uses result in MOEs that are greater than 100 and are not of concern.

For the on-farm worker scenario, dermal exposure rather than inhalation exposure contributes relatively more exposure, and is considered the "risk driver" for this type of work activity. Dermal and inhalation exposures were not combined in this assessment for the short and intermediate-term MOEs because of different toxicological endpoints of concern. However, even if dermal and inhalation exposures were combined, the overall results of the occupational risks assessment will not change.

Note that different acres treated per day assumption were used to assess risks to on-farm workers treating seeds with the dust formulation. These assumptions were based on the size of the planter being used and the amount of seed that can be planted in a day. The 180 A/day planting rate is an upper-bound estimate, based on use by some growers of 20-row corn planter. The 100 A/day planting rate is based on use of a typical 8-row to 12-row planter used by most growers.

Table 12. MOEs for Workers Treating and Planting of Seeds

Exposure Scenario (No.)	Data Source	Crop	Application Rate (lb ai/100 lb seed)	Amount Handled/ Day (lbs ai) [Acres Planted]	PPE	Short-Term MOEs	
						Dermal	Inhalation
On-Farm Seed Treatment							
Mixing/loading/ planting dry formulation (1)	Fensky study	wheat[a]	0.043	5 [100 A]	single-layer clothing, gloves, and pesticide respirator	17	1,100
				10 [200 A]		9	550
		corn[b]	0.056	0.84 [100 A]		92	6,500
				1.5 [180 A]		60	3,700
			0.125	1.9 [100 A]		48	3,000
				3.4 [180 A]		26	1,700
Mixing/loading/ planting liquid formulation-closed transfer system (2)	Helix study	wheat	0.043	13	coveralls, long-sleeved shirt, long pants, gloves, no respirator	67,000	5,900
		canola	1.5	30		29,000	2,500
			0.75	15		57,000	5,000
						Short- & Interm.-Term MOEs	
Commercial Seed Treatment							
Mixing/loading/ application of liquid formulation-treater closed system (3)	Helix study	wheat	0.043	76	coveralls, long-sleeved shirt, long pants, chemical-resistant gloves, no respirator	11,000	1,000
		canola	1.5	2640		330	30
			0.75	1320		660	60
Seed Handler bagger/sewer/ stacker (4a)	Helix study	wheat	0.043	76		37,000	2,000
		canola	1.5	2640		1,000	60

Exposure Scenario (No.)	Data Source	Crop	Application Rate (lb ai/100 lb seed)	Amount Handled/ Day (lbs ai) [Acres Planted]	PPE	Short-Term MOEs	
						Dermal	Inhalation
			0.75	1320		2,100	120
Seed Handler-forklift operator (4b)	Helix study	wheat	0.043	76	coveralls, long-sleeved shirt, long pants, chemical-resistant gloves, no respirator	119,000	16,000
		canola	1.5	2640		3,400	450
			0.75	1320		6,800	900
Seed Handler-cleaner (5)	Helix study	N/A	N/A	N/A	coveralls, long-sleeved shirt, long pants, chemical-resistant gloves, no respirator	1,800	110
Planting Treated Seed							
Loading and planting treated seed (6)	Isophenfos study	wheat	0.043 [250]	13	single-layer clothing, gloves, no respirator	920	1,200
		canola	1.5 [250]	30		400	500
			0.75 [250]	15		800	1,000

[a] Scenarios based on wheat also represent risks from use on barley, oats, and rye

[b] Scenarios based on corn also represent risks from use on sorghum

d. Occupational Incident Reports

The Agency has conducted a review of reported poisoning incidents associated with human exposure from occupational uses of lindane. The Agency has consulted the following data bases for the poisoning incident data on the active ingredient lindane: Office of Pesticide Programs (OPP) Incident Data System; Poison Control Center Data - 1993 through 1998; California Data - 1982 through 1998; and the National Pesticide Telecommunications Network.

The review only included lindane-containing products currently registered for use as a seed treatment. Incidents due to all other types of lindane products were excluded. The OPP Incident Data System includes incidents reported since 1992 from various sources, including registrants, other Federal and state health and environmental agencies and individual consumers. However, no incidents were reported in this system related to seed treatment use of lindane.

None of the cases reported to Poison Control Centers from 1993 through 1998 concerned products identified as being used for seed treatment. However, it should be noted that nearly one-third of the exposures involving lindane did not identify a specific product, but rather just exposure to lindane.

Detailed descriptions of eight cases submitted to the California Pesticide Illness Surveillance Program (1982-1998) were reviewed. In three of these cases, lindane was deemed the primary cause of the illness. All three incidents occurred in 1984 and involved driving and filling planter hoppers with treated cotton seed. Two of the cases, apparently involving the same operation, were both treated in a hospital and off work for 7 days. The third case was not treated in a hospital, but was off work for 2 days. Specific symptoms were not reported for any of these three cases. Although these incidents pertain to seed treatment activities for lindane use on cotton, which is not a registered, there is insufficient information to draw any conclusions as to whether these incidents were caused by applications in accordance with approved label instructions or by misuse of the product.

The National Pesticide Telecommunications Network did not report on incidents specifically related to lindane use for seed treatment. Relatively few incidents of illness have been reported due to lindane used for seed treatment in California.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see *Revised EFED RED Chapter for Lindane* dated July 31, 2002; *Addition of corn and canola seeds treatment use to revised Lindane RED* dated June 17, 2002; *Lindane Food Chain Bio-Accumulation, -Magnification and -Concentration* dated June 17, 2002; and *Qualitative Assessment of Long-range Transport and Atmospheric Deposition of Lindane to Great Lakes* dated June 17, 2002, which are available in the public docket and on the internet at http://www.epa.gov/pesticides/reregistration/lindane.

The lindane ecological risk assessment integrates the results of the exposure and ecotoxicity data to evaluate the potential for adverse ecological effects. The method divides exposure estimates, which are based on maximum application rates (worst case), by ecotoxicity data to derive risk quotients (RQs) for acute and chronic effects. These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a chemical, when used as directed, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a potential risk of concern to that category. The LOCs and the corresponding risk presumptions are presented in Table 13.

Table 13. LOCs and Associated Ecological Risk Presumptions

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5,	Acute risk
The acute RQ >LOC of 0.2,	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1,	Acute effects may occur in endangered species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in endangered species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
The acute RQ >LOC of 0.05	Acute effects may occur in endangered species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in endangered species

Ecological effects data requirements and assessments for seed treatment pesticides are normally based on the granular risk assessment methods. The seed treatment assessment process is designed to assess toxicological endpoints according to application rates, application method, and soil incorporation depth. Granules (seeds) are assumed to be consumed by terrestrial wildlife, and exposure may be limited by type of application method.

1. Environmental Fate and Transport

Lindane is persistent and moderately mobile. It has an estimated soil half-life of 2.6 years and a mean K_{oc} of 1368 mL/g. It is resistant to photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial actions. Because lindane is a relatively volatile, persistent and lipophilic organochlorine pesticide, it can migrate over a long distance through various environmental media such as air, water and sediment. Volatilization from soil and surface waters is a major dissipation route for lindane. To a lesser degree, lindane can also enter the air as adsorbed phase into suspended particulate matter. Lindane has often been detected in ambient air, precipitation, and surface water throughout North America, and lindane and its isomers have been detected in areas of non-use (e.g., the Arctic), indicating global atmospheric transport may occur. The source of these lindane detections is unclear, but may be the result of a combination of past

widespread use in the U.S. and other countries, its extreme persistence, and to a lesser extent, current seed treatment use which has been declining in recent years, and the pharmaceutical use of lindane.

The Great Lakes Binational Toxics Strategy, which provides a framework for actions to reduce or eliminate persistent toxic substances, especially those which bioaccumulate, from the Great Lakes Basin, was developed jointly by Canada and the United States and signed April 7, 1997. For chemicals, such as lindane, that are designated as a Level II substance under the Binational Strategy, pollution prevention activities are encouraged to reduce levels in the environment.

The presence of lindane in atmosphere, natural water bodies, soils, and sediments of the Great Lakes regions implies redeposition of lindane from secondary emissions (i.e., remobilization of lindane into the atmosphere from water bodies or ground surfaces) and long-range transport of lindane from agricultural and industrial sites. There is very limited information available to link lindane loading from global, regional, or local sources to the Great Lakes; however, reported concentrations in water samples from the channels of the Great Lakes are very similar throughout the Great Lakes, which suggest that the atmosphere is the predominant source of lindane. Some data indicate that lindane deposition from precipitation has not changed since 1990. Moreover, the Integrated Atmospheric Deposition Network (IADN) was established in 1990 by the United States and Canada to conduct air and precipitation monitoring in the Great Lakes Basin to determine the magnitude and trends of atmospheric loadings of toxic contaminants. IADN monitoring data from 1992 to 1998 indicate that the total deposition of alpha-HCH, the use which was discontinued in the U.S. in 1977 and in Canada in 1978, has significantly decreased across the Great Lakes basin, and the deposition of lindane (gamma-HCH) has also initially decreased but has remained relatively stable since 1995.

Considerable progress has been made in monitoring and assessing the loading of lindane and many other toxic contaminants for the Great Lakes regions. Nevertheless, there is limited information available to understand the importance of long-range transport and atmospheric deposition of toxic contaminants into the Great Lakes and their effects on the chronic exposure of human, terrestrial, and aquatic organisms.

2. Risk to Terrestrial Species

a. Toxicity (Hazard) Assessment

Lindane is classified as moderately toxic to birds and mammals following acute exposures. Chronic effects to birds and mammals measured by reproduction studies show adverse reproductive effects at low levels, with some effects indicative of endocrine disruption. For birds, chronic reproductive effects include significant reductions in egg production, growth and survival parameters, eggshell thinning and estradiol (a hormone associated with avian reproduction) insufficiency in female birds, which may cause a drastic reduction in the number of eggs produced. A statistically significant decrease in the number of viable embryos, live 3-week embryos and

normal hatchlings was observed when mallard duck mated pairs were fed diets containing 45 ppm or more of lindane. Chronic reproductive effects in mammals include disruption in male reproductive behavior and functioning, decreased viability in both generations of offspring, and delayed maturation of second generation pups. In addition, lindane is a lipophilic compound and has been found in milk from exposed lactating females. The acute and chronic toxicity endpoints to assess terrestrial risks from lindane use are presented in Tables 14 and 15.

b. Exposure and Risk

Terrestrial wildlife can be exposed to lindane via ingestion of treated seeds, incidental ingestion of soil while feeding or preening, ingestion of residues on soil-dwelling invertebrates and plants, dermal contact, and inhalation. The assessment below bases acute exposure on the quantity of seeds that a bird could ingest in one day and assumes the bird eats only lindane-treated seeds. This terrestrial exposure assessment differs with other assessments that are based on a lb ai/A application rate, such as risks to aquatic species and even workers handling lindane products. For instance, commodities such as corn that have a relatively lower lb ai/A application rate (0.0078 lb ai/A) that result in low aquatic and occupational risks, but have a high rate of lb ai/100 lb seed (0.125 lb ai/100 lb seed treatment rate), will result in relatively higher RQs to terrestrial species, because there is more ai on any given seed.

Birds

For avian species, acute and chronic LOCs are exceeded for all seed-treatment uses of lindane at current application rates. RQs range from 0.21-5.48 for acute risks, and 3.9-83.3 for chronic risks for currently registered crops (i.e., excluding use on canola seeds). As noted previously, RQs are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. The risk quotients are presented in Table 14 for avian risk due to ingestion of lindane-treated seeds.

Although there is acute risk to songbirds and other similar seed eating avian species, some studies have shown that birds, when given a choice of seeds, will preferentially eat seeds not treated with lindane. Waterfowl and upland gamebirds are at a reduced acute risk from seed treatment. Small birds, which consume proportionally larger quantities of food with respect to their body weight, are at greater risk than larger birds. Chronic risk to avian species may be greater during breeding season due to high seed consumption over time and the persistence of the compound in soil.

In addition, the results from two 14-day free choice avian dietary (aversion) toxicity studies suggest that bobwhite quail and red-winged blackbirds are repelled by treated seeds. These studies clearly suggested that birds avoided lindane treated food when given a choice, and even in a no-choice situation, birds did not readily eat and were emaciated at study termination. This conclusion is supported by a field study where lindane was substituted for heptaclor for treatment of seed. The results of this field study are that lindane did not produce adverse effects in birds, and residues were not detected in either their eggs or brains. This conclusion is further

supported by the fact that a lindane pesticide product was once register for use as a repellent to pheasants (EPA Reg. No. 10182-31).

Table 14. Avian Acute/Chronic RQs for Lindane

Crop	Seed concentration (lb ai/ 100 lb seed)	Acute RQs			Chronic RQs	
		Sparrow (LD_{50}= 56 mg/kg)	Red Winged Black Bird (LD_{50}=75mg/kg)	Quail (LD_{50}=122 mg/kg)	Mallard (NOAEC= 15 mg/kg)	Quail (NOAEC= 80 mg/kg)
barley	.0375	1.64	1.10	0.25	25.0	4.7
canola	1.456	63.8	42.6	9.9	970.7	182.0
	0.72	31.5	21.0	4.9	480.0	90.0
corn	0.125	5.48	3.67	0.85	83.3	15.6
	0.0558	2.45	1.64	0.38	37.2	6.9
oats	0.0313	1.37	0.92	0.21	20.8	3.9
rye	0.0328	1.44	0.96	0.22	21.9	4.1
sorghum	0.0628	2.75	1.84	0.43	41.9	7.9
wheat	0.0426	1.86	1.25	0.29	28.4	5.3

Mammals

For mammals, acute and chronic LOCs are exceeded for all seed treatment uses at current application rates. The acute and chronic RQs are based solely on dietary exposure via ingestion of lindane-treated seed. Since lindane is moderately to highly toxic to terrestrial vertebrates, low level exposures by dermal, inhalation or oral routes considered singularly or in combination, can result in significant impairment or death of exposed organisms. Furthermore, organisms which survive acute exposure and predation may still experience reproductive impairment. Smaller mammals are more vulnerable than larger mammals, especially those with high metabolic rates that dig and cache seeds. Chronic risk to mammalian species may be greater during breeding season due to high seed consumption over time and the persistence of the compound in soil. Table 15 presents the calculated risk quotients for the mammalian risk due to lindane exposures.

Table 15. Mammalian Acute/Chronic RQs for Lindane

Crop	Seed concentration (lb ai/100 lb seed)	Acute RQs (LD_{50}= 88 mg/kg)			Chronic RQs (NOAEC = 20 mg/kg)
		0.015 kg mammal	0.035 kg mammal	1 kg mammal	
barley	0.0375	0.62	0.53	0.29	19
canola	1.456	24	21	11	728
	0.72	12	10	6	360
corn	0.125	2.1	1.8	0.98	63

Crop	Seed concentration (lb ai/100 lb seed)	Acute RQs (LD_{50}= 88 mg/kg)			Chronic RQs (NOAEC = 20 mg/kg)
		0.015 kg mammal	0.035 kg mammal	1 kg mammal	
	0.0558	0.92	0.79	0.44	28
oats	0.0313	0.51	0.44	0.24	16
rye	0.0328	0.54	0.46	0.26	16
sorghum	0.0628	1.0	0.89	0.49	31
wheat	0.0426	0.70	0.60	0.33	21

3. Risk to Aquatic Species

a. Toxicity (Hazard) Assessment

The available acute toxicity data on lindane indicate that it is very highly toxic to both freshwater and estuarine species. Lindane-treated seeds planted in the ground may reach surface water bodies through runoff from the site. Because of the high toxicity of lindane, small quantities reaching surface water may kill aquatic organisms. Chronic data for freshwater organisms show that reduced growth and reproduction were the most sensitive endpoints to lindane testing. Also, no chronic toxicity data are available to assess estuarine and marine organisms. Table 16 presents the toxicity endpoints that were used to assess risk to aquatic species.

b. Exposure and Risk

Estimated environmental concentrations (EECs) used to assess potential surface water exposure to aquatic species resulting from lindane use as a seed treatment were predicted with the Tier I-Generic Estimated Environmental Concentrations (GENEEC) model. The peak EEC from the model is 0.67 ppb, and the average EEC is 0.48 ppb. At current application rates used for the seed treatment uses supported for reregistration, acute high risk and restricted use LOCs are exceeded for both freshwater and estuarine/marine organisms. The acute RQs for aquatic risk range from 0.04 to 12.2. The acute, restricted use, and endangered species LOCs are exceeded for freshwater fish (RQ= 0.55) and freshwater invertebrates (RQ= 0.94). Although the acute, restricted use, and endangered species LOCs were exceeded for estuarine/marine invertebrates (RQ= 12.2), no estuarine/marine invertebrates are currently listed as endangered. No chronic LOCs are exceeded for freshwater fish and invertebrates, although chronic risk to estuarine/marine fish could not be assessed due to a lack of toxicity data. The acute and chronic RQs are provided in Table 16. Note that lindane use on wheat seeds, which has the highest application rate in terms of lbs ai/A, was used as a surrogate to assess all seed treatment uses.

Aquatic risk estimates are conservative, because they are based on the assumption that 100% of the lindane will disassociate from the treated seed and be available to migrate to surface water after planting. However, some lindane from seed treatment may be expected to remain with

the seed/plant, or in the soil or volatilize. This assessment could be refined with a seed leaching study and use of the more refined Tier II PRZM/EXAMS surface water runoff model.

Table 16. Acute/Chronic RQs for Aquatic Species for Lindane

Crop	Freshwater				Estuarine/Marine			
	Acute RQ		Chronic RQ		Acute RQ		Chronic RQ	
	Fish (LC_{50}= 1.7 ppb)	Invert. (EC_{50}/LC_{50} =10.0 ppb)	Fish (NOAEC =2.9 ppb)	Invert. (NOAEC =54 ppb)	Fish (LC_{50}= 23 ppb)	Invert. (LC_{50}/EC_{50} =0.077 ppb)	Fish	Invert.
Wheat	0.55	0.94	0.30	0.02	0.04	12.2	Not evaluated	
Canola	1.51	2.57	0.81	0.05	0.11	33.40		

The Agency also assessed the risks associated with estimated concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies treatments. As described earlier, this "down-the-drain" releases assessment, which is based on the reported lindane concentration of discharged effluent from the Publically Owned Treatment Works (POTWs) of Sanitation Districts of Los Angeles County, California, resulted in a peak lindane surface water concentration of 3.97×10^{-4} ppb and average concentration of 3.06×10^{-5} ppb. These estimated concentrations of lindane are significantly lower than the EECs generated by the GENEEC to assess aquatic risk; therefore, use of the lindane pharmaceutical products would not result in higher aquatic RQs than those listed in Table 16.

4. Risk to Insects

Currently, EPA does not assess risk to nontarget insects; however, results of acceptable studies are used for recommending appropriate label precautions. Although lindane is highly toxic (0.2 to 0.56 μg/bee) to honeybees, risks should be low, because lindane is only used as a seed treatment application (sub-soil). However beneficial soil dwelling insects may be at risk.

5. Risk to Plants

There are no risks to plants of concern and no plant toxicity data are required. This conclusion is based upon the current use pattern, low application rate, lack of incident data on plants, and no available literature suggesting phytotoxicity.

6. Risk to Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires Federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into

context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at this time. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) as necessary.

The Agency's assessment suggests that endangered birds and especially small mammals that eat a large daily proportion of seeds may be at risk from the current seed treatment uses. Endangered freshwater fish and invertebrates may also be at acute risk. Also, exposed endangered birds, mammals and possibly fish may be at risk due to the endocrine disrupting properties of lindane combined with already limited population sizes and/or losses in critical habitat.

The endangered mammals that are potentially at risk from seeds treated with lindane are the seed-eating rodents. They inhabit beaches and arid areas and are unlikely to forage in fields with lindane-treated seeds. The risks to endangered seed-eating birds are mitigated by the fact that they are not found in the vicinity of the grain crops that are treated with lindane, and also by the results of the laboratory and field studies for lindane. These data showed that birds avoided eating seeds treated with lindane under laboratory conditions and did not show signs of intoxication through tissue residues or changes in reproductive success in field trials. Therefore, there is a "no effect" determination for endangered birds and mammals from the seed treatment use of lindane.

As discussed earlier, the model used to determine aquatic residues is conservative (it assumes that 100% of the chemical leaves the seeds and runs off into the pond) and overestimates the residues entering aquatic habitats. Therefore, the Agency does not have risk concerns to endangered aquatic species, and is requiring seed leaching data as part of this RED to confirm this determination. Once the aquatic exposure assessment is refined, the risks to endangered aquatic species will be reassessed.

The endocrine-disrupting properties of lindane require future testing under the Endocrine Disruptor Screening Program. Once these data are developed, the risk assessment for endangered species can be further refined.

In 1983, the Agency requested a "case-by-case" opinion for a Section 18 (emergency use exemption) for an at-planting, in-furrow treatment of sugarcane use in Florida. Jeopardy to the snail kite, bald eagle and Florida panther was found from potential lindane use. The Agency agreed with the jeopardy to the snail kite due to reductions to its food source (apple snails) from the sugarcane use. However, this use is no longer registered.

The Reasonable and Prudent Alternatives in the 1983 Opinion pertain to a use no longer registered and to type of exposure no longer applicable. Therefore, when the regulatory changes stipulated in this RED document are implemented, and the ecological effects and environmental fate data are submitted and accepted by the Agency, a consultation on the uses specified in this RED document may need to be initiated.

7. Ecological Incident Reports

Incident reports submitted to EPA involving lindane have been tracked by Incident Data System (IDS) and entered into a second database, the Ecological Incident Information System (EIIS). Since 1971, only four incidents which involve fish kills have been reported that are related to lindane use. However, no aquatic incidents have been reported as having occurred from treating seeds with lindane.

8. Bio-Accumulation Risks

Due to extensive use over the past 50 years, lindane is present in most environmental media and biological compartments, and is present in terrestrial and aquatic food chains. However, evidence suggests that concentrations have been gradually decreasing. The behavior of HCH isomers in the environment is complex, because they are multimedia chemicals, existing and exchanging among different compartments of the environment such as the atmosphere, surface water, soil and sediment. The most common isomers found in the environment are lindane (gamma-), alpha-, and beta-HCHs. The physical and chemical properties of these HCH isomers are quite different from one another, which likely reflect some of the differences seen in HCH isomer persistence and variability in bio-magnification, -concentration and -accumulation in the various biological compartments. Differences in accumulation are also likely due to different modes of uptake, metabolism and sources of contamination.

Bio-concentration factors (BCF) for lindane were 780x in fillet, 2500x in viscera, and 1400x in whole fish, which is partly due to high lipid solubility. Lindane can become enriched in lipid-containing biological compartments. However, although lindane may bioconcentrate rapidly, most data suggest bio-transformation, depuration, and elimination are relatively rapid once exposure is eliminated. After a 28-day exposure and 14 days of depuration, levels were reduced by 96%, 95%, and 85% in fillet, viscera, and in whole fish, respectively.

Bio-accumulation/food chain data from Russia and from Central/Western Canada suggest that lindane seems to be the least likely of the HCH isomers to bio-accumulate/bio-magnify. Other data indicate that upper trophic level mammals may be able to efficiently eliminate lindane. Even though concentrations of HCH isomers were detected in surface waters of the Arctic, bio-accumulation in the aquatic food chains was significantly less than the other organochlorine compounds analyzed.

Overall, lindane seems to accumulate in the environment, but generally to a lesser extent than either the alpha, and especially, the beta isomers. Generally, lindane tends to bio-magnify in lower trophic levels where bio-transformation was minimal; however, because upper trophic

levels are able to depurate and eliminate the compound, lindane does not appear to readily work its way up the food chain.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration, which is set forth in the reregistration eligibility decision (RED). The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing lindane active ingredients.

The Agency has completed its assessment of the dietary, occupational, and ecological risks associated with the use of currently registered pesticide products containing the active ingredient lindane. Based on a review of these data and public comments on the Agency's assessments for the active ingredient lindane, EPA has sufficient information on the human health and ecological effects of lindane to make decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA.

EPA has determined that all existing tolerances for lindane should be revoked. Consistent with longstanding EPA policy, the reason for revoking these tolerances is that they are no longer necessary because all lindane products for which the tolerances were originally established have been canceled. In reaching this conclusion, the Agency does not need to make any determination whether the exposures permitted under these tolerances would meet the FFDCA safety standard.

EPA has determined that a number of changes to the terms and conditions of registration of the seed treatment products are necessary to prevent "unreasonable adverse effects on the environment." These changes are specified in section IV.F of this document. In addition, EPA has determined that the use of lindane for seed treatment is likely to result in residues in raw agricultural commodities derived from plants grown from seeds treated with lindane. Therefore, new tolerances are required before the currently registered lindane products may be reregistered. EPA has identified additional data needed to characterize lindane metabolites in order to complete its assessment of potential dietary risks. In summary, EPA finds that the currently registered lindane seed treatment products would be eligible for reregistration if the registrants make the changes to the terms and conditions specified in this document and provide the required data, and EPA is able to establish all required tolerances for residues of lindane in food.

EPA notes that the establishment of new tolerances for the seed treatment uses of lindane is conditioned on: 1) the receipt and review of additional data to characterize lindane metabolites; and 2) EPA's ability to make a determination that establishing the new tolerances meets the safety standard in FFDCA. Because EPA does not know what the data will indicate about lindane metabolites, and for other reasons explained more fully below, EPA is unable to determine whether it will be able to make a determination that new tolerances for lindane would be safe.

FFDCA sec. 408(b)(2)(A)(i) provides that EPA may establish a new tolerance "only if . . . the tolerance is safe." The statute defines "safe" to mean "that there is a reasonable certainty that no harm will result from aggregate exposure . . .." "Aggregate exposure" includes both exposure to residues in food "and exposure from other non-occupational sources." See sec. 408(b)(2)(D)(vi).

In light of these statutory provisions, EPA is considering whether the statute requires the Agency to include in its safety assessment those exposures resulting from the use of lindane in pharmaceutical products. Lindane is currently approved by the Food and Drug Administration for use in pharmaceutical products intended to control head lice and scabies. EPA and FDA have worked together to examine the available data to assess the potential of lindane pharmaceuticals to cause adverse effects, sharing our assessments and commenting on the other agency's assessments. As discussed more fully later in this document, although the information for assessing risks is limited, the exposure and risk assessment indicates that the use of lindane for head lice control does not pose risks of concern. The limited information available on the scabies product, however, suggests that there is some possibility a portion of the patient population using lindane for scabies control may experience adverse effects. FDA has taken steps – including stronger warnings, clearer use directions, and other measures – to limit such potential adverse effects. Based on these additional steps, FDA has concluded that the therapeutic benefits of the lindane pharmaceutical products outweigh the limited potential to cause adverse effects in the patient population. Therefore, FDA regards these products as safe and effective for the purposes for which they were approved.

The existence of pharmaceutical sources of exposure to lindane raise questions of public policy and statutory interpretation that have not been resolved. These questions include: whether "aggregate exposure" encompasses exposures resulting from the use of lindane in pharmaceutical products; and if so, whether there is any reasonable statutory interpretation that could avoid apparently questionable public policy results. EPA is particularly concerned that the statute be interpreted and applied in a manner that yields results that are protective of public health and consistent with common sense. If sec. 408 were interpreted to cover exposure from pharmaceutical uses, then EPA might never be able to establish new tolerances, or to leave existing tolerances in effect, for a substance that is used both as a pesticide and a pharmaceutical product, if the pharmaceutical product caused adverse effects in humans. This result could occur regardless of the level of risk posed by the exposures permitted under the tolerance(s) and their associated pesticide registrations, and even though the pharmaceutical product has been deemed "safe and effective." In other words, EPA would be concerned about relying on an interpretation of FFDCA sec. 408 that could compel regulatory actions which would have no impact on the major source of exposure, and where the source of such exposure is fully regulated and approved under a public health standard.

EPA is interested in additional information and views that would help it determine how to approach the issues discussed above. First, because there are many uncertainties about the extent of risk from the use of lindane for scabies control, EPA encourages the development of additional information that might support a more certain assessment of the potential risks of the lindane

scabies product. EPA is also continuing to pursue a dialogue with FDA to refine aspects of the analysis. Second, EPA invites public comment on the regulatory and public policy questions raised by the use of chemicals, such as lindane, both as pesticides and pharmaceuticals. There will be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register.

Finally, EPA notes that, in addition to the reviews of lindane described above, the governments of Canada, Mexico and the United States are also considering joint actions to reduce the risks associated with lindane. Specifically, the three countries, working through the Commission for Environmental Cooperation (CEC), established by the North American Agreement for Environmental Cooperation, have agreed to develop a North American Regional Action Plan (NARAP) on lindane (CEC Council Resolution 02-07). The purpose of the NARAP is to reduce environmental and health risks from lindane on a regional basis. The Agency is also aware that internationally, other countries are taking significant actions to reduce and eliminate risks from lindane.

B. Summary of Phase 5 Comments

The Agency considered all public comments received during Phase 5 of the Public Participation Process. Comments related to new information in the risk assessment which consisted (almost exclusively) of the Agency's revised cancer assessment were also solicited. A brief summary of the comments is provided below. All of the submitted comments in their entirety are available in the public docket, and the Agency's response to the comments documents are also available in the docket and on the internet at http://www.epa.gov/pesticides/reregistration/lindane.

Comments were received by the Natural Resources Defense Council (NRDC); Beyond Pesticides; World Wildlife Fund; Alaska Department of Environmental Conservation; Farm Workers Justice Fund, Inc.; National Pediculosis Association; Alaska Community Action on Toxics; Pesticide Action Network North America; the Attorney General of the State of New York; CA Regional Water Quality Control Board; Los Angeles County, CA Sanitation District; Thompson Family Farms Ltd.; Technology Sciences Group; Uniroyal Chemical Company, and a number of individuals.

Most of the comments received pertained to the Agency's methodologies and subsequent conclusions in assessing risks associated with the use of lindane for seed treatment. For instance, some commentors disagreed with the Agency's rationale for reducing the FQPA SF; disagreed also with the Agency's cancer classification for lindane; expressed concern regarding endocrine disruption from lindane, and the Agency not including breast milk exposure in the risk assessment; recommended that risk to workers from dermal and inhalation exposure to lindane should be combined; and noted that assessed surface water concentrations of lindane exceed current EPA Water Quality Standards. Information on modern seed treatment technology was also provided that helped refine occupational risks associated with commercial seed treatment.

The Agency also received comments regarding the pharmaceutical uses (i.e., lice and scabies treatments) of lindane. Comments were received that stressed the need for the Agency to assess and consider as part of the lindane RED the direct exposure from human application of these treatments, and the environmental and human health risk that result from the disposal of this compound to waste water treatment facilities following the lice and/or scabies treatment. In response, the Agency assessed, in cooperation with FDA, the risk associated with the direct application to humans of lindane pharmaceutical products for the treatment of lice and scabies. In addition, the Agency calculated the estimated concentrations of lindane in surface water used as a source of drinking water which might result from consumer use of lindane for both lice and scabies treatments. More detailed responses to these and other comments are available in the public docket and on the internet.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

EPA assessed the risks associated with both the pesticide and pharmaceutical uses of lindane. EPA has determined that risk from exposure to lindane from agricultural uses only is within its own "risk cup" for pesticidal uses of lindane registered by EPA. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, acute and chronic food and drinking water exposure, and the potential exposure to indigenous populations in Alaska from subsistence diets. This assessment indicates that the human health risks from these combined exposures are considered to be within acceptable levels, and that the combined risks from all exposures to lindane from agricultural uses only "fit" within the individual risk cup.

The Agency also evaluated exposures and risks associated with the pharmaceutical (i.e., lice and scabies treatment) uses of lindane. As noted previously, exposures associated with the pharmaceutical use of lindane to treat lice do not pose risks of concern; however, the scabies pharmaceutical use alone exceeds the Agency's level of concern.

b. Tolerance Summary

Tolerances for residues of lindane in/on raw agricultural and animal commodities are established under 40 CFR §180.133 and expressed in terms of residues of lindane *per se* (gamma isomer of benzene hexachloride). The residue definition for lindane should be amended as follows to harmonize with International Union of Pure and Applied Chemistry (IUPAC) nomenclature: gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane. Plant commodity tolerances for lindane were originally established based on certain registered uses. Animal commodity tolerances were established based on uses which included direct livestock animal treatment as well as animal premise treatment. All of these uses have been cancelled and associated tolerances should be revoked.

The Agency considers lindane seed treatment as a food use requiring tolerances, based on existing data from radiolabeled studies which indicate uptake of lindane residues from the treated seeds into the aerial portion of the growing crop; therefore, tolerances need to be established for the existing seed treatment uses.

While the nature of the residue in livestock is adequately understood, the nature of the residue in plants is not adequately understood. Therefore, a new plant metabolism study starting from seed treatment is required for a cereal grain. The EPA concluded that the total radioactive residues (TRRs) should be used for risk assessment purposes and calculation of dietary burdens, pending receipt of additional metabolism data.

The listing of lindane tolerances under 40 CFR §180.133 should be subdivided into parts (a), (b), (c), and (d). Part (a) should be reserved for commodities with permanent tolerances, part (b) for Section 18 emergency exemptions, part (c) for tolerances with regional registrations, and part (d) for indirect or inadvertent residues.

Tolerances Listed Under 40 CFR §180.133

The established tolerances for the following commodities should be revoked: apples; apricots; asparagus; avocados; broccoli; Brussels sprouts; cabbage; cauliflower; celery; cherry; collards; cucumbers; eggplants; fat of meat from cattle, goats, horses, and sheep; fat of meat from hogs; grapes; guavas; kale; kohlrabi; lettuce; mangoes; melons; mushrooms; mustard greens; nectarines; okra; onions (dry bulb only); peaches; pears; pecans; peppers; pineapple; plums (fresh prunes); pumpkins; quinces; spinach; squash; strawberries; summer squash; Swiss chard; and tomatoes. The tolerances for these commodities are to be revoked, because the registrants do not support these uses for reregistration, and have requested that these uses be deleted from the label. These requests for use deletions have been published in the Federal Register on August 26, 1998 (Volume 63, Number 165, Page 45481-45483); September 30, 1998 (Volume 63, Number 189, Pages 52257-52260); January 27, 1999 (Volume 64, Number 17, Pages 4096-4097); August 18, 2000 (Volume 65, Number 161, Page 50524-50526); June 13, 2002 (Volume 67, Number 67, Page 40730-40732); and July 17, 2002 (Volume 67, Number 137, Page 46976-46978). Additional notices announcing these use deletions from lindane labels are to be issued soon.

Tolerances To Be Proposed Under 40 CFR §180.133

Radiolabeled studies showed uptake of lindane from seed treatment into the aerial portion of the plant; therefore, tolerances for lindane residues should be established for the treatment of wheat, barley, oats, rye, corn, and sorghum seeds with lindane. Following resolutions of residue chemistry data deficiencies, a statement in 40 CFR §180.133 should be added to specify that the established tolerances result from seed treatment only. If EPA grants the pending application for lindane use on canola seeds, a tolerance for this use is also required.

Tolerance Reassessment Summary

The Agency's tolerance reassessment summary is provided in Table 17. This table lists tolerances associated with uses that are no longer registered, as announced in several FIFRA 6(f)(1) Notices of Receipt of Requests from the registrant for cancellation and/or use deletions, which EPA approved. Therefore, the tolerances for these commodities should be revoked.

Table 17. Tolerance Reassessment Summary for Lindane

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Tolerance Listed Under 40 CFR §180.133			
Apples	1	Revoke	Uses have been deleted from the labels; therefore, tolerances should be revoked.
Apricots	1	Revoke	
Asparagus	1	Revoke	
Avocados	1	Revoke	
Broccoli	1	Revoke	
Brussels sprouts	1	Revoke	
Cabbage	1	Revoke	
Cauliflower	1	Revoke	
Lettuce	3	Revoke	
Spinach	1	Revoke	
Celery	1	Revoke	
Collards	1	Revoke	
Kale	1	Revoke	
Kohlrabi	1	Revoke	
Mustard greens	1	Revoke	
Swiss chard	1	Revoke	
Cherry	1	Revoke	
Cucumbers	3	Revoke	
Eggplants	1	Revoke	
Fat of meat from cattle, goats, horses, and sheep	7	Revoke	
Fat of meat from hogs	4	Revoke	
Grapes	1	Revoke	
Guavas	1	Revoke	
Mangoes	1	Revoke	
Melons	3	Revoke	
Mushrooms	3	Revoke	
Nectarines	1	Revoke	
Okra	1	Revoke	
Onions (dry bulb only)	1	Revoke	
Peaches	1	Revoke	
Pears	1	Revoke	

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Pecans	0.01	Revoke	
Peppers	1	Revoke	
Pineapple	1	Revoke	
Plums (fresh prunes)	1	Revoke	
Pumpkins	3	Revoke	
Quinces	1	Revoke	
Squash	3	Revoke	
Strawberries	1	Revoke	
Summer squash	3	Revoke	
Tomatoes	3	Revoke	

Codex Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for lindane in/on various plant and animal commodities. The Codex MRLs are expressed in terms of gamma HCH (fat-soluble). With respect to tolerance expression, the Codex MRL and U.S. tolerance for lindane are presently in harmony. However, the nature of the residue in plants is currently not adequately understood. Pending the results of required metabolism data, the Agency may determine that additional lindane metabolites should be included in the U.S. tolerance expression.

A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances resulting from seed treatment is presented in Table 18. The established Codex MRL and the recommended U.S. tolerances for cereal grains are not in harmony presumably because of differences in good agricultural practices. Attempts to harmonize residue limits in animal commodities cannot be made at this time because of several residue chemistry data gaps.

Table 18. Codex MRLs and Applicable U.S. Tolerances for Lindane

Codex		Reassessed U.S. Tolerance, ppm [1]	Comments
Commodity (As Defined)	MRL in mg/kg (Step)		
Apple	0.5 (CXL)[2]	Revoke	Use deleted from the label
Beans (dry)	1 (CXL) [3]	None established	Not a registered use
Brussels sprouts	0.5 (CXL)	Revoke	Use deleted from the label
Cabbage, Savoy	0.5 (CXL)	Revoke	Use deleted from the label
Cabbages, Head	0.5 (CXL)	Revoke	Use deleted from the label
Cacao beans	1 (CXL)	None established	Not a registered use
Carrot	0.2 (CXL)	None established	Not a registered use
Cauliflower	0.5 (CXL)	Revoke	Use deleted from the label
Cereal grains	0.5 (CXL) [3]	To be determined (TBD) for the grains of barley, oats, rye, and wheat	

Codex		Reassessed U.S. Tolerance, ppm [1]	Comments
Commodity (As Defined)	**MRL in mg/kg (Step)**		
Cherries	0.5 (CXL)	Revoke	Use deleted from the label
Cocoa butter	1 (CXL)	None established	Not a registered use
Cocoa mass	1 (CXL)	None established	Not a registered use
Cranberry	3 (CXL)	None established	Not a registered use
Currant, Red, White	0.5 (CXL)	None established	Not a registered use
Eggs	0.1 (CXL)	None established	
Endive	2 (CXL)	None established	Not a registered use
Grapes	0.5 (CXL)	Revoke	Use deleted from the label
Kohlrabi	1 (CXL)	Revoke	Use deleted from the label
Lettuce, Head	2 (CXL)	Revoke	Use deleted from the label
Meat of cattle, pigs, and sheep	2 (CXL)	None established	
Milks	0.1 (CXL)	None established	
Pear	0.5 (CXL)	Revoke	Use deleted from the label
Peas (pods and succulent = immature seeds)	0.1 (CXL)	None established	Not a registered use
Plums (including prunes)	0.5 (CXL)	Revoke	Use deleted from the label
Potato	0.05 (CXL)	None established	Not a registered use
Poultry meat	0.7 (CXL)	None established	
Radish	1 (CXL)	None established	Not a registered use
Rape seed	0.05 (CXL)	None established	Not a registered use
Spinach	2 (CXL)	Revoke	Use deleted from the label
Strawberry	3 (CXL)	Revoke	Use deleted from the label
Sugar beet	0.1 (CXL)	None established	Not a registered use
Sugar beet leaves or tops	0.1 (CXL)	None established	Not a registered use
Tomato	2 (CXL)	Revoke	Use deleted from the label

[1] Reassessed U.S. tolerances pending compliance by the registrants with the recommendations specified in "GLN 860.1200: Directions for Use" section of the Agency's December 11, 2001 Revised Product and Residue Chemistry Chapters for the Lindane Reregistration Eligibility Document (RED).

[2] CXL indicates that the Codex Alimentarius Commission accepted this as the final MRL for this commodity

[3] Postharvest treatment of the commodity.

c. Residue Analytical Methods

Adequate methods are available for determination of residues of lindane *per se* in/on plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists Methods I and II for the analysis of mixed isomers of 1,2,3,4,5,6-hexachlorocyclohexane in/on plant and animal commodities. Method I is a multiresidue method (see "GLN 860.1360: Multiresidue Methods: section) for the chlorinated compounds. Method II is based upon the official final AOAC method (1990, 15th edition of AOAC) and is suitable for determining residues of lindane in/on AOAC Group I nonfatty foods (vegetables and fruits), dairy products, fish, and eggs. The stated limit of detection of Method II is 0.05 ppm for most commodities.

The nature of the residue in plants resulting from seed treatment uses has not been adequately delineated; therefore, the adequacy of the available analytical methods cannot be determined. Radiovalidation of enforcement method(s) is a reregistration requirement; therefore, representative samples from the ruminant metabolism study and the required plant metabolism study should be used for radiovalidation and analyzed by the existing or proposed enforcement method(s) to determine whether total toxic residues are extracted from weathered samples (i.e., residues that were present when the crop was growing).

Based on the results of the livestock metabolism study and the required nature of the residue in plants study that is to be submitted, if the Agency determines that residues of concern include metabolites in addition to lindane *per se*, then additional crop field trial data, magnitude of the residue in poultry and cattle, and processing studies would be required. In addition, an adequate residue analytical method and storage stability data would also be required.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, lindane may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Regulatory Rationale

Provided the following risk mitigation measures are incorporated in their entirety into labels for lindane-containing products, the Agency finds that certain currently registered agricultural (seed treatment) products would be eligible for reregistration if the registrants make the changes to the terms and conditions specified in this document and provide the required data, and EPA is able to establish all required tolerances for residues of lindane in food. The regulatory rationale for each of the mitigation measures is discussed below. Where labeling revisions are warranted, specific language is set forth in Table 19.

1. Human Health Risk Mitigation

b. Dietary Risk

Acute (Food)

The acute dietary (food) risk estimate for lindane is less than 100% of the aPAD for the general population and all population subgroups. Infants (< 1 year), the most highly exposed population group, are estimated to be exposed to lindane at a level of 17% of the aPAD at the 99.9^{th} exposure percentile.

An acute dietary assessment of indigenous people in Alaska is not possible at this time, because the Agency does not have the information on a typical day's diet of indigenous people. Nevertheless, based on limited residue data, the Agency believes acute dietary (food) risks are unlikely to be of concern because indigenous adults and children would have to consume more than 50 lbs and 10 lbs, respectively, of game in a single day containing the maximum detected lindane residues to exceed the aPAD. Hence, the acute dietary (food) risk estimate is not of concern, and no additional mitigation measures are necessary to reduce these risks.

Chronic (Food)

The chronic dietary (food) risk estimate for lindane is less than 100% of the cPAD for the general population and all population subgroups usually considered. Children (1-6 years), the most highly exposed population group, are exposed to lindane at a level of 11% of the cPAD.

The chronic dietary (food) risks for indigenous people based on traditional foods are generally not of concern. For the most highly exposed population group (children 1-6 years), the subsistence diet results in lindane exposure estimates that range from 13-65 % of the cPAD, with the exception of a scenario which was 138% of the cPAD. This exception was for one community where EPA included a number of conservative assumptions discussed below. For the adult population the subsistence diet is 3-44% of the cPAD. For the risk to indigenous

populations in Alaska, the Agency believes this assessment is conservative and probably over estimates dietary risk because:

1. this assessment is based on the three communities with the highest dietary exposure (highest harvest amounts of seal, whale, and walrus) of approximately 180 Alaskan communities surveyed;
2. maximum detected residues in any game tissue were used to assess chronic exposure;
3. whale, walrus and seal blubber residues were used to assess all meat residues, even though meat is expected to have much lower lindane residues than blubber;
4. it was assumed that harvest was equal to intake (i.e., adults consume up to 2.4 lbs and children up to 1.3 lbs of meat per day); and
5. children's consumption is based on data from the diet of 7-12 year-olds while the risk assessment assumes the same amount is eaten for 1-6 year-olds.

Hence, the chronic dietary (food) risk estimate is not of concern, and no additional mitigation measures are necessary to reduce these risks.

Drinking Water - Surface

Drinking water estimated concentrations (DWECs) from surface water sources were derived from the FIRST model, which is a Tier I screening-level model designed to provide high-end estimates of potential pesticide exposure in surface water sources of drinking water. Based on the highest seed treatment/planting rate for the supported uses (wheat at 0.051 lb ai/A), the peak (acute) DWEC is 0.98 ppb and the and chronic (average) DWEC is 0.46 ppb.

Drinking Water - Ground

The Agency used the Tier I SCI-GROW screening-level model to estimate concentrations of lindane in ground water. Based on the highest planted seed treatment rate for the supported uses (wheat at 0.051 lb ai/A), both the peak (acute) and chronic (average) DWEC is 0.011 ppb.

b. Pharmaceutical Risk

Scabies Treatment

Lindane is also available, and regulated by FDA, for the treatment of scabies and head lice. The Agency's assessment of risk from use of lindane to treat scabies uses data from both animal and human blood levels, and provides a range of risk estimates. EPA's analysis using the MOE approach indicates MOEs of concern from both high and low-end treatment scenarios and using either monkey or human dermal absorption data. For the blood concentration analysis, EPA compared adjusted blood concentrations from the scabies study with blood concentration associated with short-term adverse effects in children. Based on the results of these analyses, which also factors in some of the proposed mitigation efforts to be imposed by FDA, EPA is

concerned that there is an inadequate margin of safety between blood levels associated with scabies treatment and the blood levels known to produce short-term effects in children. Note, however, that this assessment does not consider any of the medical benefits of scabies treatment.

As discussed previously in this chapter, the Agency is concerned that applying risk mitigation measures to EPA regulated pesticides uses to address risks resulting from a FDA regulated use does not represent sound public policy. This is underscored by the fact that cancellation of all EPA registered pesticide uses would not be able to reduce exposures to a level that does not exceed the Agency's level of concern.

In determining whether to approve drug for use, FDA considers the benefits associated with its use. FDA conducted a risk/benefit analysis of use of lindane as a prescription medication for scabies and concluded, based on that analysis, that lindane is safe and effective for treatment of scabies when used as labeled. The safety and potential risks from use of lindane pharmaceuticals based on safety information from the AERS database current literature were also assessed by FDA. FDA recognizes that all drugs have associated risks. Therefore, FDA must determine if the risk is acceptable when compared to non-treatment of the condition (i.e., do the potential risks or adverse side effects associated with a drug treatment outweigh the overall health benefit of treating the condition). FDA has determined that there are other therapies for the treatment of scabies that may have less risk associated with them, and thus, the label states that lindane should be reserved for patients, "who have either failed to respond to adequate doses, or are intolerant of, other approved therapies." These patients would have documented failed prior treatment with other approved products, or documented reactions, either local or systemic, to those products or drugs that would be expected to cross-react with those products. For the indication of scabies, alternative therapies are limited.

Resistance to products is also considered when evaluating drugs. At this time, there is documented resistance to lindane, which has been available since 1947. It should be noted that there is no resistance to permethrin noted in the literature to date, but with increased usage, there is a likely possibility that this will occur.

Based on this information, FDA has determined that lindane is safe and effective when used as labeled, specifically when it is used as a second-line therapy, and when it is applied in the manner and for the duration that appears in the label. Although there are other therapies available for first-line use in the treatment of scabies and lice, it is in the best interest of the public health to have several alternatives available because of existing and/or potential resistance and because of potential patient intolerance.

According to FDA, the following measures are to be implemented to reduce over-usage and increase the safe use of lindane for the treatment of scabies and pediculosis:

- The manufacturer is to make available only single-dose units of the shampoo, lotion, and cream (1-ounce packages) to reduce unnecessary, repeat applications.

- New labeling for the scabies use will exclude the volume to be described and will describe application as a thin layer.

- The current label is to be revised to indicate that lindane is for use only for patients who have attained adult stature (approximately 60 kilograms), to emphasizes that it should not be used in young pediatric patients, and that patients should be post-pubescent.

- The labeling is to be modified to more effectively communicate the appropriate use of the products (lotion and shampoo). Using the product and not following current labeled instructions has resulted in most of the adverse events.

- The labeling for lindane 1% is to include a Medication Guide, available in Spanish as well as English, that explains appropriate use and risks to the patient.

- A public information alert is to be issued to inform prescribers and the public about the correct use of lindane 1% products.

Furthermore, in accordance with Section 3 of the Best Pharmaceuticals for Children Act of 2001, provides for a research fund for the study of drugs that lack patent or exclusivity. The National Institutes of Health (NIH), in consultation with the FDA, has developed a list of drugs that would be studied. The studies would be structured by the NIH and FDA to answer questions that the FDA believes are necessary for labeling. The study request would first be issued to all holders of the drug (in lindane's case it would be the generic drug companies), who then have 39 days to say whether or not they will conduct the studies. If they decline to conduct the study, the NIH puts out a request for a proposal. If there is someone who is interested in doing the studies, they would receive the grant, and then the results of the study would become public information that can be incorporated into labeling. Lindane was recommended for placement on the list of drugs that no longer have patent and that need additional studies. Although not yet been specifically designed, FDA intends to request for general dosage and duration studies.

Lice Treatment

The Agency's assessment of risk from use of lindane to treat head lice relies on blood level data provided in two published literature studies. The highest measured blood concentration obtained following single and double treatments of head lice at label rates was significantly lower than the blood level associated with acute accidental ingestion, which resulted in short-term adverse effects according to the cited case study article. Therefore, the Agency does not believe that lindane pharmaceutical products used for treatment of lice pose human health risks of concern when used in accordance with directions provided on the label. In addition, there are documented cases of resistance to all treatments that are currently indicated for the treatment of head lice.

The current label and package volume for lindane shampoo is being changed consistent with changes being made for the lindane lotion and include the same warnings and information. The only difference will be the condition being treated and the instructions for use.

Drinking Water Risks from Pharmaceutical Uses

The Agency used an exposure model to assess the risks associated with estimated concentrations of lindane in surface water from consumer use for both lice and scabies treatments. Surface water concentrations were based on the average of reported lindane concentrations in discharged effluent (0.03 ppb) from the Publically Owned Treatment Works (POTWs) of Sanitation Districts of Los Angeles County, California.

As part of this assessment, the Agency assumed that the reported concentration of lindane from wastewater treatment was discharged and instantaneously diluted into surface water where no further removal (e.g., degradation, absorption, volatilization) occurs. Also, different stream dilution factors, which are the volume of receiving stream flow compared with the volume of wastewater released from the POTW, were assumed to estimate acute and chronic DWECs from surface water sources. Based this information, the acute DWEC is 3.97×10^{-4} ppb and the chronic DWEC is 3.06×10^{-5} ppb for the pharmaceutical use only of lindane. The Agency believes that a conservative approach was used to estimate acute and chronic DWECs, because of the instantaneous and upper-end stream dilution factors that were assumed in the assessment. Therefore, because the DWECs are extremely low, and are considered upper-end values due to the conservative assumptions used in the assessment, the Agency does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies treatments.

c. Risk for All Registered Pesticide Lindane Exposures

For lindane, risk assessments were conducted that included the combined risk from food and drinking water exposures only. For acute and chronic exposure, the Agency uses the DWLOC as a surrogate measure of risk associated with exposure from pesticides in drinking water. The DWLOC is then compared with the DWEC to determine whether there is a potential concern for exposure and risk.

Acute Risk

Based on the registered uses of lindane, the highest surface water acute DWEC of 0.98 ppb and ground water acute DWEC of 0.011 ppb resulted from lindane use on wheat seeds. As indicated in Table 5, these DWECs are less than the acute DWLOC of 170 ppb for the most sensitive population subgroup (infants < 1 year); therefore, acute risks associated with food and drinking water exposures to lindane are not of concern to the Agency, and no further mitigation measures are necessary.

Chronic Risk

Based on the registered uses of lindane, the highest surface water chronic DWEC of 0.46 ppb and ground water chronic DWEC of 0.011 ppb resulted from lindane use on wheat seeds. As

indicated in Table 5, these DWECs are less than the chronic DWLOC of 14 ppb for the most sensitive population subgroup (children 1-6 years); therefore, chronic risks associated with food and drinking water exposures to lindane are not of concern to the Agency, and no further mitigation measures are necessary.

Special Populations

For the indigenous people of the Arctic region of the U.S. (Alaska), the Agency has insufficient quantitative information on lindane concentrations in Alaskan drinking water sources to estimate chronic exposure to lindane in food and drinking water is of concern to the Agency. However, it is expected that the background environmental levels of lindane in Alaska are much less than the calculated chronic DWEC (0.46 ppb) for surface water sources from seed treatment uses of lindane. Nevertheless, the chronic DWEC of 0.46 ppb, which is based on seed treatment use, is significantly less than the calculated chronic DWLOC of 6 ppb for children and 31 ppb for adults. The chronic DWLOC calculations are derived from the conservative subsistence dietary food exposure estimates for all but the one Alaskan community which resulted in 138% of the cPAD being consumed by the children (1-6 years) subpopulation. For the reasons discussed previously, the Agency believes this assessment is conservative and probably overestimates dietary risk; therefore, and chronic dietary risk does not pose a risk concern to the Agency and not further measures are necessary to mitigate these risks.

d. Occupational Risk

On-Farm Seed Treatment

Dust Formulation

As indicated in Table 12, for the currently registered seed treatment uses (excluding canola), on-farm treatment with the dust formulation (scenario 1) is below the target MOE of 100 and is of concern to the Agency. Because of the rate of seeds planted per acre, the risk associated with the use of the dust formulation on wheat seeds (dermal MOEs 9-17), which is representative of barley, oats, and rye, is much higher than the risk for lindane use on corn seeds (dermal MOEs 26-92), which is representative of sorghum. In response to these risk concerns, the registrant has voluntarily agreed to discontinue on-farm treatment with the dust formulation for wheat, barley, oats, and rye, and reduce the maximum application rate for corn from 0.125 lb ai/100 lb seed to 0.0558 lb ai/100 lb seed. As a result of this rate reduction, the corresponding dermal MOEs for on-farm treatment of corn and sorghums seeds with the dust formulation are 60 and 92, depending upon the size of the planter and the amount of seed planted in a day. Inhalation MOEs are 3,700 and 6,500 respectively, and are not of risk concern. However, wheat, barley, oats, and rye seeds may still be treated with the liquid formulation on-farm with the use of a closed transfer system, or at a commercial treatment facility (see below).

Thus, the remaining uses that are available for on-farm treatment with the dust formulation are corn and sorghum seeds. Based on the proposed lower seed treatment rate and the seeding

rate of 15 lbs seed/A for corn, the estimate amount of lindane applied to the field is 0.00837 lb ai/A. Although the maximum application rate for lindane use on sorghum is slightly higher (0.0628 lb ai/100 lb seed) than for corn, the typical seeding rate is much lower (6.76 lbs seed/A), resulting in a rate of 0.00425 lb ai/A of lindane being applied to the field when planting sorghum seeds. As a result, the total amount of lindane being handled by workers and the associated risk to treat and/or plant 180 acres of sorghum in a day will be about 2X less than the amount of lindane and risks to treat and/or plant corn. Hence, risks associated with on-farm treatment of corn seeds are protective of the risks for treating sorghum seeds with lindane.

As stated previously, the assessed risks to workers treating corn and sorghum seeds with the dust formulation were based on the size of the planter and the amount of seed planted in a day. MOEs were calculated for the amount of seeds that need to be treated to plant 180 A/day and 100 A/day. The 180 A/day is an upper-bound estimate, based on use by some growers of a 20-row corn planter. However, the Agency recognizes that the typical sized planter used by corn growers is 8-row to 12-row. It is estimated that a grower using a 8-row or 12-row planter will only be able to plant about 100 A in a work day, when including the amount of time needed to treat the seed with the dust formulation. As indicated in Table 12, the risks associated with treating corn with the dust formulation at the proposed lower application rate, and assuming the grower is using a typical 8-row or 12-row planter, result in an MOE of 92, which is slightly below the target MOE of 100 and not of concern to the Agency.

As noted in Table 12, the PPE utilized in the chemical-specific exposure study was single-layer clothing, gloves, and a respirator, which resulted in dermal MOEs for on-farm treatment of corn and sorghum seeds with the dust formulation are less than the target MOE. To mitigate the dermal risk concern, especially for the MOE of 60 at a planting rate of 180 A/day, double-layer clothing (coveralls over single-layer clothing) needs to be employed. The Agency believes that this added PPE is adequately protective to reduce dermal exposure below the level of concern. Moreover, the calculated inhalation MOEs, which are based on the use of a half-mask, dual cartridge respirator equipped with an organic vapor cartridge and dust filter, are significantly greater than the target MOE. Because of this substantial MOE exceedance, it is appropriate to reduce the level of inhalation PPE for workers treating corn and sorghum seeds on-farm with the dust formulation to a dust/mist respirator for products that contain lindane only as the active ingredient. The Agency acknowledges that there are some end-use products that contain other active ingredients in addition to lindane, and that the use of more protective PPE may be necessary, because of the inclusion of these other active ingredients in the product formulation. The Agency believes that this reduction on inhalation PPE is protective and will not result in exposures of concern. Therefore, to mitigate on-farm treatment of corn and sorghum seeds with the dust formulation, the following mitigation measures needs to be implemented:

- workers must wear double layer clothing (coveralls over long-sleeved shirt and long pants, chemical-resistant footwear), chemical-resistant gloves, and a dust/mist respirator; and
- reduce the maximum application rate for corn to 0.0558 lb ai/100 lb seed.

Furthermore, the exposure study for lindane treatment of wheat seeds from which the risk estimates for scenario 1 were derived involved workers scooping pesticide from open 10 lb bags of product and mixing the pesticide in the seed hopper with a stick. It is likely that some of the exposure to these workers occurred during the removal of lindane from the bag with a hand-held scoop. Current packaging for some end-use products of the dust formulation is much smaller (1.5 oz) and pre-measured for ease of use (one packet per seed hopper). In addition, some end-use products are also packaged in a small cylindrical container that is inserted into a tube applicator, which applies the product to the seed while the tube is inserted into the seed, thus minimizing potential exposure to the dust formulation. The tube is also used as a device to mix the product with the seed. Although not all registered products of the dust formulation are packaged in small pre-measured packets or cylindrical containers to be used with a tube applicator/mixing device, that Agency acknowledges that these efforts help further reduce exposure to workers. However, the Agency does not believe that these specific packaging and application device measures are necessary to be imposed for all end-use product labels.

Liquid Formulation

The other scenario of on-farm treatment of seeds with the liquid formulation using a closed transfer system resulted in MOEs significantly greater than the target MOE of 100 and are not of concern. Therefore, for the on-farm treatment of seeds with the liquid formulation in a closed transfer system for currently registered uses (scenario 2), no further measures are necessary to mitigate these risks. Because the calculated dermal MOEs are significantly greater than the target MOE, and current practices specified by the Worker Protection Standard allow a reduction of PPE when engineering controls are used, it is appropriate to reduce the level of PPE utilized during the surrogate exposure study. Workers treating seeds on-farm with the liquid formulation using a closed transfer system are to use single-layer clothing (long-sleeved shirt, long pants, shoes and socks), gloves, and a chemical-resistant apron. The Agency believes that these PPE reductions are protective and will not result in exposures of concern.

Commercial Seed Treatment

As indicated in Table 12, the MOEs associated with the work activities in treating seeds with lindane in a commercial facility are above the target MOE of 100 and are not of concern to the Agency, except for two scenarios that involve treatment of canola seeds (scenarios 3 and 4a). Therefore, for the treatment of seeds currently registered, no further measures are necessary to mitigate these risks, provided the PPE utilized during the surrogate exposure study are employed (i.e., double-layer clothing and gloves). However, because the calculated dermal MOEs are significantly greater than the target MOE, and the Agency traditionally allows handlers to reduce their PPE when using engineering controls, it is appropriate to reduce the level of PPE for workers in commercial seed treatment facilities to single-layer clothing (long-sleeved shirt, long pants, shoes and socks) and gloves, and a chemical-resistant apron. The Agency believes that these PPE reductions are protective and will not result in exposures of concern.

Planting Treated Seed

The scenario of loading and planting treated seed (including canola), whether treated on-farm or received from a commercial facility, resulted in MOEs greater than the target MOE of 100 and are not of concern. Therefore, no further measures beyond the PPE utilized in the surrogate study are necessary to mitigate these risks (scenario 5), which includes single layer clothing (long-sleeved shirt, long pants, shoes and socks) and gloves.

Post-Application Risk

Because lindane is used in agriculture only as a seed treatment, EPA has determined that post-application exposure to agricultural workers is unlikely as long as workers are not performing tasks that involve contact with or disruption of the soil subsurface where treated seed has recently been planted. In accordance with the Worker Protection Standard (WPS), the restricted-entry interval (REI), based on the acute toxicity of technical lindane (Table 11), is 24 hours. Note, however, that under the "No Contact" early entry exception in the WPS, workers may reenter treated areas during the REI once the application is finished as long as they will not contact anything that has been treated with the pesticide. Therefore, the Agency has no risk concerns for post-application exposures to agricultural workers, and no risk mitigation measures are necessary beyond the 24 hour REI. Also, provided the soil is not disturbed and there is no contact with the treated seeds, workers may enter the planted field during the 24-hour REI.

2. Environmental Risk Mitigation

The Agency's assessment suggests that the use of lindane can result in adverse acute and chronic effects to terrestrial organisms, and adverse acute effects to aquatic organisms. Lindane is a potential endocrine disruptor in birds, mammals, and possibly fish.

Birds

The Agency has acute and chronic risks of concern for birds that may be exposed to lindane. For the currently registered uses of lindane, the RQs for acute exposure range from 0.21 to 5.48, and the RQs for chronic exposure range from 3.9 to 83.3. The highest RQs for acute and chronic risks are based on lindane use on corn seeds. To help mitigate occupational risks associated with on-farm treatment of corn seeds, the registrant has agreed to reduce the maximum application rate from 0.125 to 0.0558 lb ai/100 lb seed; thereby reducing the highest acute RQ for from 5.48 to 2.75, and the highest chronic RQ from 83.3 to 41.9. Currently, almost all corn seed treatment occurs on-farm, however, the corresponding rate for commercial seed treatment will also be lowered to 0.0558 lb ai/100 lb seed. With the reduction of the corn application rate, the maximum application rates for all of the registered uses of lindane are comparable (within a factor of about 2X or less), which results in the corresponding avian RQs also being in the same range.

In addition, the results of two avian dietary aversion toxicity studies suggest that birds are repelled by treated seeds. These studies clearly suggested that birds avoided lindane treated food

when given a choice, and even in a no-choice situation, birds did not readily eat and were emaciated at study termination. In fact, lindane was once register for use as a repellent to pheasants. This conclusion is also supported by a field study where lindane was substituted for heptaclor for treatment of seed. It was determined from this study that lindane did not produce adverse effects in birds and residues were not detected in either their eggs or brains. Hence, the Agency believes that the risk to birds by treating certain seeds with lindane are lower than the current risk assessment suggests and not of concern; therefore, no further measures are necessary to mitigate these risks.

Mammals

Similar to birds, the Agency has acute and chronic risks of concern for mammals, particularly small mammals that eat and cache seeds. For the currently registered uses of lindane, the RQs for acute exposure range from 0.24 to 2.1, and the RQs from chronic exposure range from 16 to 63 with the highest RQ based on corn use as well. To help mitigate occupational risks associated with the on-farm treatment of corn seeds, the registrant has agreed to reduce the maximum application rate from 0.125 to 0.0558 lb ai/100 lb seed. Reducing the maximum application rate will also reduce the highest acute RQs from 2.1 to 1.0, and the chronic RQ from 63 to 31. Likewise with the avian risk assessment, this measure results in the maximum application rates and corresponding mammalian RQs for all of the registered uses of lindane to be comparable (within a factor of about 2X or less).

It is important to note that because mammals hold territories, the peak RQs discussed in this section only apply to local populations of mammals that dig and feed on seeds, and where lindane treated seeds are planted. On average, approximately 6% of the corn and 1% of the sorghum that is planted in the U.S. is treated with lindane. The Agency believes that the local population of mammals that may be exposed to lindane treated seed is low. Moreover, although there are no data available to demonstrate that mammals avoid consuming lindane treated seeds as do birds, mammals may be similarly adverse to eating seeds treated with lindane. Therefore, actual exposure to mammals could be lower. For these reasons, the Agency believes that no further measures are necessary to mitigate these risks.

Aquatic Species

The Agency has acute risks of concern for freshwater fish and invertebrates, and estuarine marine invertebrates, with RQs that range from 0.55 to 12.2. The chronic risk RQs for freshwater fish and invertebrates are less than 1.0 and are not of concern to the Agency. EPA has not received any chronic aquatic toxicity data for estuarine and marine fish or invertebrates.

Aquatic risks are based on a Tier I surface water runoff model (GENEEC), and the assumption that 100% of the compound will disassociate from the seed surface, which has likely produced conservative estimates that overestimate the environmental concentrations and resulting risks to aquatic species. Actual aquatic risks are expected to be lower; therefore, the Agency

does not have risk concerns to aquatic species, and is requiring seed leaching data as part of this RED to confirm this determination.

Endangered Species Statement

The Agency is currently engaged in a Proactive Conservation Review with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of lindane use to Federally listed threatened and endangered species. At that time, the Agency will also consider any regulatory changes recommended in the RED document that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to lindane at levels of concern.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, will soon be proposed for public comment in the Federal Register in 2002.

E. Labeling Statements

Other use and safety information needs to be placed on the labeling of all end-use products containing lindane. For the specific labeling statements, refer to Section V of this document

For manufacturing-use products, the following statement needs to be added on the label: "This pesticide is toxic to fish, birds, and other wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the USEPA."

For end-use products, the following statement needs to be added on the label: "This product is toxic to fish, birds, and other wildlife. Exposed treated seeds may be hazardous to birds and other wildlife. Dispose of all excess treated seeds by burial away from bodies of water. Do not contaminate water by disposing of equipment washwaters. Apply this product only as specified on the label."

F. Lindane Risk Mitigation Summary

The following is a summary of the risk mitigation measures that are necessary to be incorporated in their entirety into labels for lindane-containing products. Specific language for these revisions is set forth in Table 19 of this document. Likewise, the data required to be provided to the Agency to confirm these regulatory decisions are also listed in Section V.

- Prohibit on-farm treatment of wheat, barley, oats, and rye with the lindane dust formulation.

- Reduce maximum application rate for corn to 0.0558 lb ai/100 lb seed.

- Workers must wear double layer clothing (coveralls over long-sleeved shirt and long pants, chemical-resistant footwear), chemical-resistant gloves, and a dust/mist respirator for on-farm treatment of corn and sorghum seeds only with the dust formulation.

- A 24 hour REI for all seed treatment uses.

- All lindane end-use product labels need to specify a 30-day plantback interval for leafy vegetables and a 12-month plantback interval for all other unregistered crops. The registrant has the option to conduct a confined accumulation of rotational crops (OPPTS 860.1850) study to potentially reduce these plantback intervals.

V. What Registrants Need to Do

EPA finds that the currently registered lindane seed treatment products would be eligible for reregistration if the registrants make the changes to the terms and conditions specified in this document and provide the required data, and EPA is able to establish all required tolerances for residues of lindane in food. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section V.*D* below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. For lindane technical grade active ingredient products, registrants need to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI):

(1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

(2) submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

(1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Mark Howard at (703) 308-8172 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
Mark Howard
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Mark Howard
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient lindane, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

(1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

(2) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

(1) two copies of the confidential statement of formula (EPA Form 8570-4);

(2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

(3) five copies of the draft label incorporating all label amendments outlined in Table 19 of this document;

(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

(5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

(6) the product-specific data responding to the PDCI.

Please contact Karen Jones at (703) 308-8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (PDCI/PRB)
Karen Jones
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Karen Jones
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration determination of lindane for the above uses has been reviewed and determined to be substantially complete. However, the following data requirements are necessary to confirm the reregistration decision documented in this RED:

Product and Residue Chemistry

- OPPTS 830.1550, Product identity and description
- OPPTS 830.1620, Description of the production process
- OPPTS 830.6314, Oxidation/reduction: chemical incompatibility
- OPPTS 830.6316, Explodability
- OPPTS 830.6317, Storage stability
- OPPTS 830.6320, Corrosive characteristic
- OPPTS 830.7050, UV/Visible light absorption

The Agency acknowledges that data in response to these and other product and residue chemistry study requirements (i.e., OPPTS 830.1600, 830.1700, 830.1750) included in the 1985 Registration Standard DCI for lindane have been submitted to the Agency and are being reviewed. Even though data have been submitted, the data requirements listed above are included in the generic DCI accompanying this lindane RED document.

- OPPTS 860.1300, Nature of residue (plant metabolism study). A new nature of the residue study is required for application of lindane as a seed treatment to a cereal grain. This data requirement is included in the 1985 Registration Standard DCI for lindane and remains outstanding. Because this data requirement is listed in the 1985 DCI, it is not being repeated in the DCI accompanying this lindane RED document.

Environmental Fate

- Seed leaching (Special Study, OPPTS guideline number not yet established)

If, after submission of an acceptable cereal grain seed treatment metabolism study, the Agency determines the residues of concern to include metabolites in addition to lindane *per se*, the following additional data will be required, and are listed in the DCI accompanying this RED document as reserved:

- OPPTS 860.1500, Crop field trials for wheat and corn (Reserved)
- OPPTS 860.1480, Magnitude of the residue in poultry and cattle (Reserved)
- OPPTS 860.1520, Processed food/feed (Reserved)
- OPPTS 860.1340, Residue analytical method (Reserved)
- OPPTS 860.1380, Storage stability (Reserved)

2. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 19 at the end of this section.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination regarding eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A PDCI, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 19 at the end of this section.

C. Existing Stocks

Existing stocks time frames are established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy;" *Federal Register*, Volume 56, No. 123, June 26, 1991. The Agency has determined that registrants may distribute and sell lindane products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

Table 19 describes how language on the labels should be amended to incorporate the risk mitigation measures outlined in Section IV.

Table 19: Summary of Labeling Changes for Lindane

Description	Labeling	Placement on Label
Manufacturing-Use Products		
Formulation Instructions Required on All MUPs	"Only for formulation into an ***insecticide*** for the following use(s)" *[fill blank only with those uses that are being supported by MP registrant*]. "Dust formulations made from this MUP are for on-farm treatment of corn and sorghum seeds only." "Liquid formulations made from this MUP are for commercial or on-farm seed treatment for barley, wheat, corn, oats, rye, and sorghum with a closed transfer system only."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	**"Environmental Hazards"** "This pesticide is toxic to fish, birds, and other wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the USEPA."	Precautionary Statements

Description	Labeling	Placement on Label
End-Use Products Intended for Occupational Use		
Handler PPE Guidelines (all formulations)	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain Lindane, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. For **multiple-active-ingredient** end-use products that contain Lindane, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7. PPE that will be established on the basis of Acute Toxicity testing on end-use products undergoing product reregistration must be compared with the active ingredient PPE specified below by the RED. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Handler PPE Statements
PPE Established by the RED for Dust Formulations.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" [*registrant inserts A,B,C,D,E,F,G,or H*] "on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators and other handlers, including persons handling or planting treated seeds, must wear: - Coveralls over long-sleeved shirt and long pants - Chemical-resistant footwear plus socks - Chemical-resistant gloves - A NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N, R, P, or HE filter." *Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" filter designation must be dropped from the above respirator statement.*	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals

Description	Labeling	Placement on Label
PPE Established by the RED for Liquid Formulations.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." "Handlers using closed systems and handlers planting or otherwise handling treated seed must wear: - Long-sleeved shirt and long pants, - Shoes plus socks, - Chemical-resistant gloves, - Chemical-resistant apron when mixing, loading or treating seeds on farm." "Handlers exposed to the concentrate while performing tasks such as equipment or spill clean-up, for which engineering controls are not feasible must wear: - Coveralls over long-sleeved shirt and long pants, - Chemical-resistant footwear plus socks, - Chemical-resistant gloves, - Chemical-resistant apron." "See engineering controls for additional requirements."	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Immediately following the PPE requirements
Engineering Controls for Dust Formulations	"When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Immediately following the User Safety Requirements

Description	Labeling	Placement on Label
Engineering Controls for Liquid Formulations (*only products marketed in closed system compatible packages will be eligible for Reregistration for on-farm seed treatment*)	"Engineering Controls" "Seeds must be treated useing a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for dermal protection, and must: -- wear the personal protective equipment required above handlers using a closed system, -- wear protective eyewear if the system operates under pressure, and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the PPE specified for handlers exposed to the concentrate that are performing tasks for which engineering controls are not feasible."	Precautionary Statements: Immediately following the User Safety Requirements
User Safety Recommendations	**"User Safety Recommendations"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Immediately following Engineering Controls) Must be placed in a box
Environmental Hazards	**"Environmental Hazards"** "This product is toxic to fish, birds, and other wildlife. Exposed treated seeds may be hazardous to birds and other wildlife. Dispose of all excess treated seeds by burial away from bodies of water. Do not contaminate water by disposing of equipment washwaters. Apply this product only as specified on the label."	Precautionary Statements: Immediately following the User Safety Recommendations

Description	Labeling	Placement on Label
Restricted Entry Interval (REI).	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours:" "Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated."	Agricultural Use Requirements Box.
Early Entry PPE	PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls worn over short-sleeve shirt and short pants, * chemical-resistant gloves made of any waterproof material, and * chemical-resistant footwear plus socks."	Agricultural Use Requirements Box.
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use

Description	Labeling	Placement on Label
Other Risk Mitigation Restrictions	**All Formulations:** Labels must be amended to reflect a reduced application rate for corn of 0.0558 lbs of a.i. per 100 lb seed. Labels must reflect the following maximum application rates for wheat: 0.0426 lbs of a.i. per 100 lb seed; barley: 0.0375 lbs of a.i. per 100 lb seed; oats: 0.03125 lbs of a.i. per 100 lb seed; rye: 0.0328 lbs of a.i. per 100 lb seed; sorghum: 0.0628 lbs of a.i. per 100 lb seed. A plant-back interval of 30 days for leafy vegetables and 12 months for all unregistered crops must be placed on the label. **Dust Formulations:** "This product may only be used as an on-farm seed treatment for corn and sorghum." (*All other crop sites must be removed from the label*) **Liquid Formulations:** "This product may only be used as a commercial or on-farm seed treatment for barley, wheat, corn, oats, rye, and sorghum." *(All other crop sites must be removed from the label*) "Labels attached to the treated seed must read: Persons handling treated seed must wear long-sleeved shirt and long pants plus chemical-resistant gloves made out of any waterproof material. Treated seed must not be used or mixed with food or animal feed or processed for oil. Exposed treated seeds may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water. Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated."	Directions for Use

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VI. Appendices

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APPENDIX A: Lindane Use Patterns Reflecting Label Changes

Crop	Formulation and % ai	EPA Reg. No.	Maximum Seed Treatment Rate (lbs ai/CTW seed)	Maximum Planting Rate (lbs seed/A)
Corn	8.6% RTU	554-140	0.0558	14
	18.75% Dust	554-142, 7501-37, 34704-737, 42056-15		
	25% Dust	1381-165, 7501-38, 7501-112, 34704-674, 42056-11,66330-19		
	99.5% Powder (Technical Product)	655-28, 5481-225, 19713-61,19713-91,40083-1		
	18.75% RTU	7501-152		
	16.6% Dust	42056-14		
Sorghum	99.5% Powder (Technical Product)	655-28, 5481-225, 19713-61, 19713-191, 40083-1	0.0628	9
	25% Dust	7501-38		
	16.6% Dust	42056-14		
	18.75% Dust	42056-15		
Barley	40% EC	400-490, 544-144	0.0375	96
	8.6% RTU	554-140		
	99.5% Powder (Technical Product)	655-28, 5481-225, 19713-61, 19713-191		
	30% FC	7501-34, 19713-387		
	25% RTU	7501-78		
	8% RTU	7501-141		
	18.75% RTU	7501-152		
	30% EC	19713-401		
	25% EC	34704-674		

Crop	Formulation and % ai	EPA Reg. No.	Maximum Seed Treatment Rate (lbs ai/CTW seed)	Maximum Planting Rate (lbs seed/A)
Oats	40% EC	400-490, 554-144	0.03125	80
	8.6% RTU	54-140		
	99.5% Powder (Technical Product)	655-28, 5481-225, 19713-61, 19713-191, 40083-1		
	30% FC	7501-34, 19713-387		
	8% RTU	7501-141		
	18.75% RTU	7501-152		
	30% EC	19713-401		
	25% EC	34704-674		
	6.5% RTU	42056-16		
Rye	40.0% EC	400-490, 554-144	0.0328	84
	8.6% RTU	554-140		
	99.5% Powder (Technical Product)	655-28, 5481-225, 19713-61, 19713-191, 40083-1		
	30% FC	19713-387		
	30% EC	19173-401		
	25% EC	34704-674		
	6.5% RTU	42056-16		
Wheat	40% RTU	400-490	0.0426	120
	8.6% RTU	554-140		
	40% EC	554-144		
	99.5% Powder (Technical Product)	655-28, 5481-225, 19713-61, 19713-191, 40083-1		
	30% FC	7501-34, 19713-387		
	30% EC	19713-401		

Crop	Formulation and % ai	EPA Reg. No.	Maximum Seed Treatment Rate (lbs ai/CTW seed)	Maximum Planting Rate (lbs seed/A)
	25% RTU	7501-78		
	25% EC	34704-674		
	6.5% RTU	42056-16		

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APPENDIX B: Data Supporting Guideline Requirements for the Reregistration of Lindane

GUIDELINE REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Study Title		
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	Data Gap
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	45426601
830.1620	61-2A	Description of production process	All	Data Gap
830.1670	61-2B	Formation of Impurities	All	45426601
830.1700	62-1	Preliminary Analysis	All	45426602, 45426603, 45426604, 45426605
830.1750	62-2	Certification of limits	All	Acceptable*
830.1800	62-3	Analytical Method	All	45426606
830.6302	63-2	Color		00072468
830.6303	63-3	Physical State		00118743
830.6304	63-4	Odor		00102995
830.7050	None	UV/Visable Absorption		Data Gap
830.7200	63-5	Melting Point		00118743
830.7300	63-7	Density	All	00072468
830.7840 830.7860	63-8	Solubility (Shake Flask Method)	All	00118712
830.7950	63-9	Vapor Pressure	All	00118743
830.7550	63-11	Octanol/Water Partition Coefficient	All	00160130
830.6313	63-13	Stability	All	00072468
830.6314	63-14	Oxidizing/Reducing Action	All	45426607, Data Gap (Sept.1985 DCI)
830.6316	63-16	Explodability	All	Data Gap
830.6317	63-17	Storage Stability	All	45426609, Data Gap (Sept.1985 DCI)
830.6320	63-20	Corrosion characteristics	All	Data Gap

GUIDELINE REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Study Title		
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity	ABN	00161629, 00020560, 00160000
850.2200	71-2A	Avian Dietary Toxicity - Quail	ABN	0002293, 40056103, 40056104
850.2200	71-2B	Avian Dietary Toxicity - Duck	AB	44867101
850.2400	71-3	Wild Mammal Toxicity	AB	Reserved
850.2300	71-4A	Avian Reproduction - Quail	AB	44812201
850.2300	71-4B	Avian Reproduction - Duck	AB	44867101
850.2500	71-5(b)	Terrestrial Wildlife Field Test		Waived
850.1075	72-1A	Fish Toxicity Bluegill	AB	40094602, 40098001
850.1075	72-1C	Fish Toxicity Rainbow Trout	AB	40098001, 40094602
850.1010	72-2A	Invertebrate Toxicity	ABN	40094602
850.1010	72-2B	Invertebrate Toxicity - TEP	ABN	40094602, 40098001
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	AB	40098001
850.1055	72-3B	Estuarine/Marine Toxicity - Mollusk	AB	44355501, 00161764, 40098001
None	72-3C	Estuarine/Marine Toxicity - Shrimp	AB	40094602, 40098001
850.1400	72-4A	Fish- Early Life Stage-Freshwater	AB	44405401, 40056105
None	72-4B	Estuarine/Marine Invertebrate Life Cycle	AB	44405402, 40056106
850.1450	72-4D	Freshwater Invertebrate Life-Cycle	AB	44405402, 40056106
850.1850	72-6	Aquatic Food Chain Transfer		40056102
850.3020	141-1	Honey Bee Acute Contact	AB	00036935, 05001991

GUIDELINE REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Study Title		
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	ABN	00049330
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	ABN	00109141
870.1300	81-3	Acute Inhalation Toxicity-Rat	ABN	00161631
870.2400	81-4	Primary Eye Irritation-Rabbit	ABN	00161632
870.2500	81-5	Primary Skin Irritation	ABN	00161633
870.2600	81-6	Dermal Sensitization	ABN	00161634
870.6200	81-8	Acute Neurotoxicity Screen		44769201
870.3100	82-1A	90-Day Feeding - Rodent	ABN	Satisfied under 870.4300
870.3150	82-1B	90-Day Feeding - Non-rodent	ABN	Satisfied under 870.4300
870.3200	82-2	21-Day Dermal - Rabbit/Rat	ABN	41427601
870.3250	82-3	90-day Subchronic Dermal Toxicity Test, Rat	ABN	41427601
870.3465	82-4	90-Day Inhalation-Rat	ABN	00145073, 40873501
870.3800		Reproductive & Fertility Effects		42246101
870.6200	82-5b	90-day neurotoxicity - mammal		44781101
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	ABN	Satisfied under 870.4300
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	ABN	Satisfied under 870.4300
870.4200	83-2A	Oncogenicity - Rat	ABN	Satisfied under 870.4300
870.4200	83-2B	Oncogenicity - Mouse	ABN	45291402
870.4300	83-5	Combined chronic toxicity/ oncogenicity feeding – Rat	ABN	41094101, 41853701, 42891201
870.3700	83-3A	Developmental Toxicity - Rat	ABN	00062656, 42808001
870.3700	83-3B	Developmental Toxicity - Rabbit	ABN	00062658, 42808002 (both studies supplemental when considered together)
870.3800	83-4	2-Generation Reproduction - Rat	ABN	00049330, 42246101
870.5140	84-2A	Gene Mutation (Ames Test)	ABN	00142715
870.5300	84-2	Gene Mutation in Mammalian Cells	ABN	00144500
870.6200	81-8A	Acute Neurotoxicity Screening Battery- Rat	ABN	44769201
870.6200	81-8B	Subchronic Neurotoxicity Screening Battery- Rat	ABN	44781101
870.6300	83-6	Developmental Neurotoxicity- Rat	ABN	45073501
870.7600	85-2	Dermal Penetration	ABN	40056107, 40056108

GUIDELINE REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Study Title		
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2400	133-3	Dermal Passive Dosimetry Exposure	ABN	45200002, 44405802, 42251901, 44731501
875.2500	133-4	Inhalation Passive Dosimetry Exposure	ABN	45200002, 44405802, 42251901, 44731501
None	231	Estimation of Dermal Exposure at Outdoor Sites	AB	45200002, 44405802, 42251901, 44731501
None	232	Estimation of Inhalation Exposure at Outdoor Sites	AB	45200002, 44405802, 42251901, 44731501

GUIDELINE REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Study Title		
ENVIRONMENTAL FATE				
None	160-5	Chemical Identity	ABN	Acceptable*
835.2120	161-1	Hydrolysis	AB	00161630
835.2240	161-2	Photodegradation - Water	AB	00164545, 00164547, 44793101
835.2410	161-3	Photodegradation - Soil	AB	44440605
835.2370	161-4	Photodegradation - Air	AB	Waived
835.4100	162-1	Aerobic Soil Metabolism	AB	40622501
835.4200	162-2	Anaerobic Soil Metabolism	AB	Data gap (Sept.1985 DCI)
835.1240	163-1	Leaching/Adsorption/Desorption	AB	00164346, 00164538, 40067301
835.1410	163-2	Laboratory Volatilization (from Soil) Study	AB	Waived
835.6100	164-1	Terrestrial Field Dissipation	AB	40622502, 44867103
835.6300	164-3	Forestry Field Dissipation		Waived
None	165-3	Accumulation in irrigated crops		Waived
850.1730	165-4	Bioaccumulation in Fish	AB	40056101, 40056102
None	165-5	Bio-accumulation, non target		Reserved (Sept.1985 DCI)
835.SS01	None	Seed Leaching Study	AB	Data Gap
RESIDUE CHEMISTRY				
860.1100	171-2	Chemical Identity	ABN	Acceptable*
860.1300	171-4A	Nature of Residue - Plants	AB	1985 Lindane Reregistration Standard*, 00025707, 00060143, 00060150, 00105413, 44383001, 44383002, 44405403, Data Gap (Sept. 1985 DCI)
860.1300	171-4B	Nature of Residue - Livestock animals	AB	1985 Lindane Reregistration Standard*, 40271301, 40271302, 44405404, 44867104, 45224101, 45224102, 45277201, 40271301
860.1340	171-4C	Residue Analytical Method - Plants	AB	1985 Lindane Reregistration Standard*, 05006312, 40431202, 40431206 , 44383003 , 44383004, 44909901, Reserved
860.1340	171-4D	Residue Analytical Method - Animals	AB	1985 Lindane Reregistration Standard*, 00025690, 00032233, 00099909, 05002348, 05003005, 40431208, 44440601, 44867105, Reserved

GUIDELINE REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Study Title		
860.1380	171-4E	Storage Stability-Plants	AB	40431203, 40431205, 41699701, 44440602, 44909901 Data Gap (Sept. 1985 DCI)
860.1380	171-4E	Storage Stability-Animals	AB	40660502, 44440603, 44867106, Reserved (Sept. 1985 DCI)
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	AB	1985 Lindane Reregistration Standard*, 00025685, 00045126, 00075989, 00088048, 00088165, 00089592, 00101478, 00104441, 00118722, 00118723, 00118724, 00118725, 00118739, 40660503, 40660504, 40660505, 40660501, 44440604, Reserved
860.1500	171-4K	Crop Field Trials - Corn	AB	Reserved
860.1500	171-4K	Crop Field Trials - Wheat	AB	Reserved
860.1520	171-4L	Process Food/Feed - Corn	AB	Reserved
860.1520	171-4L	Process Food/Feed - Wheat	AB	Reserved
860.1850	165-1	Confined Rotational Crop study	AB	Waived
860.1900	165-2	Field Rotational Crop Study	AB	Reserved

* No MRID assigned.

APPENDIX C: EPA's Technical Support Documents for Lindane

All technical support documents for the lindane RED may be viewed either on paper at the OPP Public Docket or via the Internet. The paper documentation in support of this RED is maintained in the OPP docket: Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 am to 4 pm. Electronic copies of these documents are maintained at the following sites: www.epa.gov/pesticides/reregistration/status.htm (the OPP website) or http://cascade.epa.gov/RightSite/dk_public_home.htm, under docket number OPP-2002-0202 (EPA's e-dockets site).

These documents include the following:

Human Health Risk Assessment Documents

17. Rebecca Daiss (USEPA/OPPTS/OPP/HED). Revised HED Risk Assessment for Lindane. July 31, 2002.
18. Rebecca Daiss (USEPA/OPPTS/OPP/HED). Revised Assessment of Risk from Use of Lindane for Treatment of Lice and Scabies. July 30, 2002.
19. Thurston Morton (USEPA/OPPTS/OPP/HED). Revised Anticipated Residues and Dietary Risk Analysis. December 13, 2001.
20. Thurston Morton (USEPA/OPPTS/OPP/HED). Revised (Product and Residue) Chemistry Chapter. December 11, 2001.
21. Thurston Morton (USEPA/OPPTS/OPP/HED). Revised Dietary Risk and Exposure Estimate for Lindane Through Subsistence Diets for Indigenous People of Alaska. April 17, 2002.
22. Suhair Shallal. (USEPA/OPPTS/OPP/HED). Toxicology Chapter. September 28, 2000.
23. Brenda Tarplee (USEPA/OPPTS/OPP/HED). FQPA Safety Factor Report. August 2, 2002.
24. Suhair Shallal. (USEPA/OPPTS/OPP/HED). Lindane - A Second Report of the Hazard Identification Assessment Review Committee. June 18, 2001.
25. Suhair Shallal and Sanjivani Diwan. (USEPA/OPPTS/OPP/HED/CARC). Cancer Assessment Document: Evaluation of Carcinogenic Potential of Lindane. November 29, 2001.
26. David Jaquith. (USEPA/OPPTS/OPP/HED). Lindane: Revision of Exposure Assessment for Commercial Seed Treatment Plant Worker. April 23, 2002.
27. David Jaquith. (USEPA/OPPTS/OPP/HED). Revision of Exposure Assessment for Planting of Seed Treated with Lindane. April 24, 2002.

28. David Jaquith. (USEPA/OPPTS/OPP/HED). Revision of Exposure Assessment of Workers for On Farm Seed Treatment with Lindane Using Open and Closed Systems and Planting Treated Seed. June 4, 2002.

Environmental Fate and Ecological Effects Documents

29. Nick Federoff (USEPA/OPPTS/OPP/EFED). Revised EFED RED Chapter for Lindane. July 31, 2002.
30. Nick Federoff (USEPA/OPPTS/OPP/EFED). Addition of Corn and Canola Seed Treatment Use to Revised Lindane RED. June 17, 2002.
31. Faruque A. Khan (USEPA/OPPTS/OPP/EFED). Qualitative Assessment of Long-Range Transport and Atmospheric Deposition of Lindane to [the] Great Lakes. June 17, 2002.
32. Faruque A. Khan (USEPA/OPPTS/OPP/EFED). Correction in Qualitative Assessment of Long-Range Transport and Atmospheric Deposition of Lindane to Great Lakes. July 31, 2002.
33. Nick Federoff (USEPA/OPPTS/OPP/EFED). Lindane Food Chain Bio-Accumulation, Magnification, and Concentration. June 17, 2002.
34. Faruque A. Khan (USEPA/OPPTS/OPP/EFED). Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotions Into Household Wastewater. April 25, 2002.

Use, Usage, and Benefits Documents

35. Istanbul Yusuf (USEPA/OPPTS/OPP/BEAD). Quantitative Usage Analysis of Lindane. February 27, 2002.
36. David Brassard (USEPA/OPPTS/OPP/BEAD). BEAD's Impact Analysis of the Seed Treatment Use of Lindane on Wheat, Barley, Oats, Rye, Corn, Sorghum, and Canola. February 5, 2002.
37. David Brassard (USEPA/OPPTS/OPP/BEAD). BEAD Review of Korpalski Handler Exposure Assessment for Lindane Use as a Seed Treatment in the US. May 15, 2002.
38. David Brassard (USEPA/OPPTS/OPP/BEAD). Revised Number of Acres Treated per Day for Lindane Seed Treatment Use on Field Corn. June 26, 2002.

APPENDIX D: MRID Bibliography for Lindane

GUIDE TO APPENDIX D.

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

MRID	Citation
00016455	Dill, R.; Mobley, J.E. (1976) Evaluation of CGA-43089 as a Safener on Grain Sorghum Where Dual Is Applied Preemergence: Test No. SE OH 318 76. (Unpublished study received Dec 14, 1976 under 100- EX-54; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 229063-D)
00016457	Gagnon, S.A. (1976) Evaluate CGA-43089 Seed Treatment for Protection of Sorghum Treated with CGA-24705 Herbicide Treatments: Test No. OW OH 534 76. (Unpublished study received Dec 14, 1976 under 100-EX-54; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:229063-F)
00020560	Schafer, E.W. (1972). The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21(?):315-330. (Also in unpublished submission received Apr 25, 1978 under 476-2180; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233577-C)
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APPENDIX E: Generic Data Call In (DCI)

See the following table for a list of generic data requirements for lindane. Please note that a complete Data Call In (DCI) will be sent to registrants under separate cover, pending approval from the Office of Management and Budget (OMB).

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APPENDIX F: Product Specific Data Call In

See the following table for a list of product-specific data requirements for lindane. Please note that a complete Data Call In (DCI) will be sent to registrants under separate cover, pending approval by the Office of Management and Budget.

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APPENDIX G: EPA'S Batching of Lindane Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing lindane as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If

a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirty-one products were found which contain lindane as the active ingredient. These products have been placed into five batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Batch 5: EPA Reg. No. 34704-653 and 66330-19 may not rely on the acute inhalation (81-3) data conducted on EPA Reg. No. 7501-38.
- No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient
	655-28	99.5
	5481-225	99.5
	19713-61	99.5
	19713-191	99.5
	40083-1	99.5

Batch 2	EPA Reg. No.	% Active Ingredient
	7501-34	30.0
	19713-387	30.0

Batch 3	EPA Reg. No.	% Active Ingredient
	19713-262	25.0
	34704-674	25.0

Batch 4	EPA Reg. No.	% Active Ingredient
	7501-37	Lindane: 18.75 Carboxin: 20.00 Maneb: 35.00

Batch 4	EPA Reg. No.	% Active Ingredient
	7501-152	Lindane: 18.75 Carboxin: 20.00 Maneb: 35.00

Batch 5	EPA Reg. No.	% Active Ingredient
	7501-38	Lindane: 25.00 Captan: 12.24
	34704-653	Lindane: 25.00 Captan: 12.50
	66330-19	Lindane: 25.00 Captan: 12.50

No Batch	EPA Reg. No.	% Active Ingredient
	400-490	40.00
	554-140	Lindane: 8.60 Maneb: 25.60
	554-142	Lindane: 18.75 Maneb: 50.00
	554-144	40.00
	1381-165	Lindane: 25.00 Captan: 15.00 Diazinon: 15.52 Metalaxyl: 1.00
	7501-78	Lindane: 10.53 PCNB: 17.68
	7501-112	Lindane: 25.00 Carboxin: 14.00 Diazinon: 15.00
	7501-141	Lindane: 8.00 Carboxin: 14.00 Thiram: 12.00
	8660-53	25.00
	19713-401	30.00
	34704-658	25.00

No Batch	EPA Reg. No.	% Active Ingredient
	34704-737	Lindane: 18.75 Maneb: 50.00
	42056-11	Lindane: 25.00 Captan: 14.67 Diazinon: 15.00
	42056-14	Lindane: 16.60 Captan: 32.75
	42056-15	Lindane: 18.75 Mancozeb: 50.00
	42056-16	Lindane: 6.50 Mancozeb: 20.00

APPENDIX H: List of Registrants Sent DCI

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APPENDIX I: List of Electronically Available Forms

Pesticide Registration Forms are available (in PDF format and require the Acrobat reader) at the EPA internet site: http://www.epa.gov/opprd001/forms/ .

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.' If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

   a. Registration Division Personnel Contact List
   OO. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   pp. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the

Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.